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Committee on the Internal Market and Consumer Protection

2003/0256(COD)

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OPINION

of the Committee on the Internal Market and Consumer Protection

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 – C5-0531/2003 – 2003/0256(COD))

Draftsman (*): Hartmut Nassauer

(*) Enhanced cooperation between committees – Rule 47 of the Rules of Procedure

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SHORT JUSTIFICATION

Since the Commission presented its draft regulation on reforming EU policy on chemicals on 29 October 2003, there has basically been a consensus about the need to revise the current legal provisions governing the safe use of chemicals in the European Union. The draft text has nevertheless encountered substantial resistance with regard to a whole range of details. The main criticism is of the Commission's chosen methodology for the registration of substances, whereby the information requirements are based primarily on the volume of a substance which is manufactured or imported.

The draft legislation will have unusually far-reaching effects. It covers not only the chemicals industry and its downstream users, but also the metal-working industry, the motor vehicle industry, the textile sector, etc. Those affected are substance producers just as much as distributors, downstream users and importers, i.e. all those who deal with chemicals as part of their business: apart from a few conglomerates, primarily small and medium-sized firms, including tradesmen.

Weakness of the Commission's draft text

The Commission has met the most determined resistance over the system that it is proposing for the registration of substances. The Commission links the scale of the information to be supplied by the registrant to the volume of the substance which is manufactured or imported. The information requirements start with the manufacture or import of 1 tonne per year and increase, step by step, for the manufacture or import of 10 tonnes per year, 100 tonnes per year and 1000 tonnes per year.

The crucial weakness of the Commission's approach is that it requires data without any reference to the actual risks posed by substances. The data requirements increase as the tonnage thresholds are crossed, without this necessarily being justified by increased risk to humans and the environment.

This volume-based approach has undesirable effects. The direct costs alone of supplying the information about a substance range from € 20 000 to € 400 000, depending on the volume-based data requirements. The unavoidable consequence of this is that for small production volumes, in particular, the registration costs will in many cases be totally disproportionate to turnover. As a result, it is to be feared that a substantial number of substances – estimates range upwards from 20% – and products will be withdrawn from the market. The Commission's tonnage threshold method thereby creates a false incentive regarding substance selection which is based on registration costs and not on substance risk.

The draftsman's proposal for improvement

The draftsman therefore proposes to supplement the Commission's tonnage thresholds with risk-based factors. The new concept does not look at every conceivable use of a substance, but focuses the data requirements on typical types of exposure undergone by humans and the environment in connection with certain categories of use. Typical exposure situations requiring the same protective measures are grouped together. These are the main types of absorption (oral, dermal or by inhalation) where humans are concerned and the ways in which substances get into the environment (air, water or soil), supplemented in each case by the

duration of exposure (once or short-term, occasional, repeated or long-term). Within these exposure categories individual uses are grouped together in areas of use (industrial, commercial or private use). If all the actors, from the manufacturer to the last downstream user, work with these exposure categories and categories of use, an initial risk assessment will require only a core set of data. This must reliably provide the essential physico-chemical properties of a substance and its acute effects on humans and the environment. Further data requirements, and in particular further tests, should then depend on the individual exposure scenario. Increasing levels of exposure would mean stricter requirements for the registration procedure with regard to time and content.

Such core information will at the same time enable the Agency to classify the substances to be registered in groups according to their inherent risk, and thus determine priorities for registration. Using this system, too, the registration of all existing substances covered by REACH should be completed in 11 years.

Advantages of the modified approach

With this approach the starting-point for the registration system is not the volume of a substance, but the risk pertaining to it. The costs involved in registration will thus be reduced, but not at the expense of health and environmental protection. Manufacturers and users will no longer have to focus on a vast multiplicity of individual uses in making their risk assessment, but on a manageable number of categories. This will reduce the notification requirements applicable to downstream users and the flow of information in the production chain will be made easier. At the same time, business confidentiality and commercially significant information will be better protected. Moreover, there will be greater flexibility with regard to the use and availability of substances, and this will tangibly reduce the undesirable economic result whereby substances disappear from the market only because the testing and registration costs are commercially unsustainable. Animal testing can also be substantially reduced by this approach. The combination of exposure categories and categories of use with a set of core information thus constitutes an effective instrument for protecting humans and the environment in a more targeted way, i.e. according to actual exposure, and simultaneously for reducing the overall outlay on resources and administration by both firms and authorities.

If the Commission wishes to attain the goal that it has itself set of maintaining and enhancing the competitiveness of the EU chemicals industry the draft REACH text must become more practical, more workable, less costly and more plausible in terms of the system adopted. The new chemicals policy must serve to protect human health and the environment, but must also be conducive to conditions for investment and innovation which will actually allow new jobs and companies to be created and not allow existing ones to disappear. Part of this is a REACH approach which links data requirements to the risk inherent in a substance, and not to the fact that not all scientifically conceivable findings are available about every substance. By adopting a different system for the registration of substances this opinion attempts to do justice to this requirement.

AMENDMENTS

The Committee on the Internal Market and Consumer Protection 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	Amendments by Parliament
Amendment 1	
Recital 3 a (new)	
	(3a) Pursuant to the action plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development, chemicals must, by 2020, be produced and used in a way which is not damaging to human health and the environment.
Justification	
The new chemicals legislation on REACH should be put into the global context of the international commitment on chemicals as adopted at the World Summit on sustainable development in 2002.	
Amendment 2	
Recital 8	
(8) Responsibility for the management of the risks of substances should lie with the enterprises that manufacture, import, place on the market or use these substances.	(8) Responsibility for the management of ***and for the information on*** the risks of substances should lie with the enterprises that manufacture, import, place on the market or use these substances.
Justification	
Preliminary to the introduction of 'duty of care' in further amendments.	
Amendment 3	
Recital 10	
(10) The evaluation provisions provide for follow-up to registration, by checking that registrations are in compliance with the requirement of this Regulation and by allowing for generation of more information	(10) The evaluation provisions provide for follow-up to registration, by checking that registrations are in compliance with the requirement of this Regulation and by allowing for generation of more information

on the properties of substances. ***Member States should*** evaluate such substances if *they have* reasons for suspecting that such substances present a risk to health or the environment***, after having included them in their rolling plans***.	on the properties of substances. ***The Agency evaluates*** such substances if ***it has*** reasons for suspecting that such substances present a risk to health or the environment.

Justification

The evaluation of substances must be carried out centrally, by the Agency, in order to ensure uniform evaluation criteria. The Agency's position must therefore be substantially strengthened, and the mechanisms for cooperation between it and the national authorities must be spelled out clearly.

Amendment 4
Recital 15a (new)

	(15a) The Agency must be the guarantor of legal certainty for enterprises, and must therefore have the sole competence for the evaluation of the risk associated with substances and on test results. This also means that the burden of proof lies with an enterprise or Member State which questions an evaluation by the Agency.

Justification

Uniform, reliable and legally certain conditions for the evaluation of substances and for the implementation of decisions throughout the European Union are needed. They can only be guaranteed by a strong Agency.

Amendment 5
Recital 16

(16) Experience has shown that it is inappropriate to require Member States to assess the risks of all chemical substances. ***This*** responsibility should therefore be given, in the first place, to the enterprises that manufacture or import substances, but only when they do so in quantities exceeding a certain volume, to enable them to carry the associated burden. Those enterprises should take the necessary risk management	(16) Experience has shown that it is inappropriate to require Member States to assess the risks of all chemical substances. ***The*** responsibility ***of fulfilling the duty of care*** should therefore be given, in the first place, to the enterprises that manufacture or import substances, but only when they do so in quantities exceeding a certain volume, to enable them to carry the associated burden. Those enterprises should take the necessary

measures in accordance with their assessment of the risks of their substances.	risk management measures in accordance with their assessment of the risks of their substances ***and pass on relevant recommendations along the supply chains***. ***This includes measures such as the transparent and appropriate description, documentation and notification of the risks stemming from the production, use and sale of their substances.***

Justification

Rewording of original Amendment 3. Producers pass on their recommendations on risk management measures along the supply chain. Users decide on appropriate implementation. A reference to selecting the safest available substance is superfluous as this follows logically and as required from the measures taken.

Amendment 6
Recital 17

(17) In order to undertake chemical safety assessments of substances effectively, manufacturers and importers of substances should obtain information on these substances, if necessary by performing new tests.	(17) In order to undertake chemical safety assessments of substances effectively, manufacturers and importers of substances should obtain ***the necessary*** information on these substances ***for the purpose of risk assessment and safe use based on actual exposure***, if necessary by performing new tests.

Justification

In order to avoid animal testing and reduce costs, only animal tests which are genuinely necessary for a risk assessment on the basis of actual exposure and use may be carried out. It is therefore inappropriate to vary the scale of the testing and data requirements according to production or import volumes.

Amendment 7
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***	(20) Since producers and importers of articles should be responsible for their articles, it is appropriate to impose a registration requirement on ***dangerous*** substances which are intended to be released

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.	from articles.

Justification

Preliminary to amendment to Article 6 on substances in articles: linked to amendment 53.

Amendment 8
Recital 21

(21) ***The requirements for undertaking*** chemical safety ***assessments by manufacturers*** and ***importers should be prescribed in detail in*** a ***technical annex to allow them to meet their obligations***. To ***achieve fair burden sharing with their customers, manufacturers*** and ***importers should in their chemical safety assessment address not only their own uses and*** the ***uses for which they place their substances on the market, but also all uses which their customers ask them*** to ***address***.	(21) ***To ensure that a*** chemical safety ***assessment*** and ***the communication thereof along the product chain, as well as the assumption of responsibility throughout*** a ***product's life are carried out efficiently, the evaluation of substances should be based on both their inherent properties and the exposure actually expected in association with certain uses.*** To ***that end, exposure and use categories are used. Instead of looking at individual product groups and uses, typical types of exposure undergone by humans*** and the ***environment are identified and classified, without reference*** to ***the use of a substance. This enables typical exposure situations requiring the same protective measures to be grouped together. Such situations cover the main types of absorption in humans (oral, dermal or by inhalation), the ways in which substances get into the environment (air, water or soil) and the duration of exposure (once or short-term, occasional, repeated or long-term). Within these exposure categories substances are defined and then grouped together: basic areas of use (industrial, commercial or private use) and the degree or stages of exposure which is/are tolerable***.

Justification

Rewording of original Amendment 5. It is not feasible for a substance manufacturer to undertake detailed individual evaluations for all conceivable conditions of use. Furthermore, from the point of view of downstream users this would also be undesirable. Too detailed a description of the conditions of use restricts the flexibility that downstream users need with regard to use of a substance. In instances in which the special exposure scenario does not fit the actual situation in which a substance is used either a more comprehensive transfer to the manufacturer of (possibly sensitive) applied know-how would be needed, or the downstream user would have to carry out the evaluation of the substance himself. The communication of exposure categories which were not dependent on use, instead of exposure scenarios specific to defined uses, would alleviate this problem.

Amendment 9
Recital 23

(23) One of a group of multiple registrants should be allowed to submit information on behalf of the others according to rules which ensure that all the required information is submitted, while allowing sharing of the costs burden.	(23) One of a group of multiple registrants should be allowed to submit information on behalf of the others according to rules which ensure that all the required information is submitted, while allowing sharing of the costs burden. ***However, appropriate guidelines should be adopted to guarantee the accessibility and the representation of SMEs in this consortia.***

Justification

In order to make such consortia affordable for SMEs, appropriate measures should be taken to guarantee their representation and to defend their interests.

Amendment 10
Recital 25

(25) If tests are performed, they should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, and good laboratory practice, set out in Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of	(25) If ***new*** tests are performed ***on vertebrate animals***, they should comply with the relevant requirements of protection of laboratory animals, set out in Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes, and good laboratory practice, set out in Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of

laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances.	laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests on chemical substances.

Justification

The considerably more onerous and more expensive requirements of good laboratory practice should apply only to new tests which need to be carried out on vertebrate animals. While providing the same degree of safety, this would markedly improve the cost efficiency of the registration requirements.

Amendment 11
Recital 38 a (new)

(38a) In order to support firms which belong to consortia, the Commission is required to draft guidelines for compliance with competition law.

Amendment 12

Recital 41 a (new)

(41a) The development of an appropriate, coherent, risk-based 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 deriving from the use of an article containing chemical substances. The possibility should also be assessed of providing additional information via websites and educational campaigns in order to respond to the right of consumers to be informed about the articles they use. This will increase the safe use of chemical substances and products derived from them, and will reinforce consumer confidence as regards the use of articles containing chemical substances.

Justification

The development of a communication system is essential in order to increase consumer confidence.

Amendment 13
Recital 42

(42) As the existing safety data sheet is already being used as a communication tool within the supply chain of substances and preparations, it is appropriate to develop it further and make it an integral part of the system established by this Regulation.	(42) As the existing safety data sheet is already being used as a communication tool within the supply chain of substances and preparations, it is appropriate to develop it further and make it an integral part of the system established by this Regulation. ***However, other methods of communicating information on the safe use of substances and preparations should be considered for consumers.***

Amendment 14
Recital 43

(43) In order to have a chain of responsibilities, downstream users should be responsible for assessing the risks arising from their uses of substances if ***those uses are*** not covered by a safety data sheet received from their suppliers, unless the downstream user concerned takes more protective measures than those recommended by his supplier or unless his supplier was not required to assess those risks or provide him with information on those risks; for the same reason, downstream users should manage the risks arising from their uses of substances.	(43) In order to have a chain of responsibilities, downstream users should be responsible for assessing the risks arising from ***the relevant exposure based on*** their uses of substances if ***such exposure is*** not covered***, at least as regards the exposure category,*** by a safety data sheet received from their suppliers, unless the downstream user concerned takes more protective measures than those recommended by his supplier or unless his supplier was not required to assess those risks or provide him with information on those risks; for the same reason, downstream users should manage the risks arising from their uses of substances.

Justification

It is not feasible for a substance manufacturer to undertake detailed individual evaluations for all conceivable conditions of use. Furthermore, from the point of view of downstream users this would also be undesirable. Too detailed a description of the use or safe conditions of deployment restricts the flexibility that downstream users need with regard to use of a substance. In instances in which the special exposure scenario does not fit the actual situation

in which a substance is used either a more comprehensive transfer to the manufacturer of (possibly sensitive) applied know-how would be needed, or the downstream user would have to carry out the evaluation of the substance himself. The communication of exposure categories which were not dependent on use, instead of exposure scenarios specific to defined uses, would considerably reduce these drawbacks.

Amendment 15
Recital 45

(45) For enforcement and evaluation purposes, downstream users of substances should be required to report certain information if their use is outside the conditions of the exposure scenario detailed in the safety data sheet communicated by their original manufacturer or importer and to keep ***such*** reported information up-to-date.	(45) For enforcement and evaluation purposes, downstream users of substances should be required to report certain information if their use is outside the conditions of the exposure scenario ***or the categories of exposure and use*** detailed in the safety data sheet communicated by their original manufacturer or importer and to keep ***the*** reported information up-to-date.

Justification

Rewording of original Amendment 12 as a result of introducing categories of use and exposure. See detailed justification for Amendment 1 to Recital 21.

Amendment 16
Recital 47

(47) A significant number of animals would have to be used in testing to fulfil the more demanding information requirements in respect of certain substances, if those information requirements were automatically applied. Significant costs for enterprises may be associated with testing. It is therefore necessary to ensure that generation of such information is tailored to real information needs; ***to this end*** evaluation ***should require Member States to prepare decisions and*** the Agency ***to decide on the programmes of testing proposed*** by manufacturers and importers ***for such substances. The Member State in which the manufacture takes place or the importer is established should*** be ***responsible for the***	(47) A significant number of animals would have to be used in testing to fulfil the more demanding information requirements in respect of certain substances, if those information requirements were automatically applied. Significant costs for enterprises may be associated with testing. It is therefore necessary to ensure that generation of such information is tailored to real information needs ***on the basis of exposure***; ***in connection with the*** evaluation the Agency ***should examine the registration documents submitted*** by manufacturers and importers ***and require further tests to*** be ***carried out if necessary***.

evaluation of testing proposals.

Justification

See amendments relating to Recitals 10 and 15a (new) (central role for the Agency), and also Recitals 29b (new) and 43 (minimum data initially; further tests on the basis of actual exposure).

Amendment 17
Recital 54 a (new)

(54a) The authorisation procedure should, in general, be based on the registration and take into account the existing risk management measures for certain categories of exposure and use that the registration mentions. Applications which are already adequately controlled should be excluded from the authorisation by means of decisions of general validity ('positive list'). In addition, uses of substances which are already regulated under the Restrictions Directive (Directive 76/769/EEC) or which will in future come under Title VIII (Restrictions), should not be regulated as part of the authorisation.

Justification

Follows from the introduction of categories of exposure and use.

Amendment 18
Recital 55 a (new)

(55a) In the case of substances which are considered as being liable to an authorisation requirement, following registration the Agency should examine whether their use is already adequately controlled, e.g. by means of a restriction in Annex XVI. If this is not the case and if the conditions for restrictions pursuant to Title VIII exist, a restriction procedure should be initiated. The restricted substance should then be exempted from

	the authorisation requirement. Should the examination by the Commission provide adequate control, the substance should be exempted from the authorisation requirement at that stage; the exemption decision may not be postponed until the decision on inclusion in Annex XIII.

Justification

The use of substances is regulated under both the restriction and the authorisation process. The two procedures are not sufficiently aligned with, and separate from, each other. There is a risk of inconsistent decisions and duplication for firms and authorities.

Amendment 19
Recital 69

(69) The Agency should be central to ensuring that *the* chemicals *law* and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public. The confidence in the Agency of the Community institutions, the Member States, the general public and interested parties is therefore essential. For this reason, it is vital to ensure its independence, high scientific, technical and regulatory capacities, transparency and efficiency.	(69) The Agency should be central to ensuring that chemicals *legislation* and the decision-making processes and scientific basis underlying it have credibility with all stakeholders and the public, ***so that the general public and all interested parties have confidence in the safety of the substances and preparations they use. It should also play a pivotal role in coordinating communication on REACH (including communication on the risks for consumers) and in its implementation.*** The confidence in the Agency of the Community institutions, the Member States, the general public and interested parties is therefore essential. For this reason, it is vital to ensure its independence, high scientific, technical and regulatory capacities, ***sound communications expertise,*** transparency and efficiency.

Amendment 20
Recital 90

(90) Regular reports by the Member States and the Agency on the operation of this	(90) Regular reports by the Member States and the Agency on the operation of this

Regulation will be an indispensable means of monitoring the implementation of chemicals legislation as well as trends in this field; conclusions drawn from findings in the reports will be useful and practical tools for reviewing the Regulation and, where necessary, for formulating proposals for amendments.	Regulation will be an indispensable means of monitoring the implementation of chemicals legislation as well as trends in this field; conclusions drawn from findings in the reports will be useful and practical tools for reviewing the Regulation and, where necessary, for formulating proposals for amendments. ***To this end, the Commission shall undertake an ex post-impact assessment of the Regulation after the first five years of its implementation, to assess if the Regulation met the initially set targets and if the functioning of, and competition within, the internal market has been preserved.***

Justification

Considering the importance of the regulatory system REACH sets up, it is necessary to evaluate the results achieved in the first years of implementation in order to check whether the initial targets can be met, and if not, to make the necessary adjustments.

Amendment 21
Recital 91, subparagraph 1 a (new)

	The Agency and Member States should allow access to information in accordance with Directive 2003/4/EC and Regulation (EC) 1049/2001 on Public Access to Environmental Information and with the UN/EEC Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters (the 'Aarhus Convention'), to which the European Community is a party signatory.

Justification

The REACH Regulation must conform to Article 2 of the Aarhus Convention, which provides for access to information in the environmental field, with specific reference to substances and emissions and to human health.

Amendment 22
Recital 100 a (new)

100a. Waste, as defined in Directive 75/442/EEC as amended, is not a substance, preparation or article within the meaning of Article 3 of this Regulation. This Regulation only applies to substances in waste through the obligation to take account of the waste stages of a substance as such, in a preparation or in an article in the chemical safety assessment. The full life-cycle of a substance should be addressed at registration in the chemical safety assessment and be reflected in the safety data sheets. The waste stage of substances has to be considered in the development of exposure scenarios. However, if the recovery of waste results in the manufacture of a new substance, preparation or article through a process of transformation, the provisions of this Regulation apply to this new substance, preparation or article.

Justification

Alignment of Recitals with the changes for waste and recycling proposed in Articles 2 and 4.

Amendment 23
Recital 104 a (new)

104a. For reasons of workability, wastes and materials used as secondary raw material or as a source of energy, shall be exempted.

Generating value ('valorisation') from wastes and/or materials used as secondary raw material, or as a source of energy, in recovery operations contributes to the EU objective of sustainable development. REACH should not introduce requirements that could potentially hamper recycling and recovery and thereby increase the need to use non-renewable resources.

Amendment 24

Article 1, paragraph 1

1. This Regulation ***lays down provisions on*** substances ***within the meaning of Article 3(1). These provisions shall apply to the manufacture, import, placing*** on the market ***or use of such substances on their own, in preparations or in articles, if so stated***.	1. ***The purpose of*** this Regulation ***is to ensure the free circulation of chemical*** substances on the ***internal*** market.

Justification

The purpose of the Regulation should be stated at the outset.

Amendment 25
Article 1, Paragraph 2

2. ***The purpose of*** this Regulation is ***to ensure the free circulation of such substances*** on the ***internal*** market.	2. This Regulation is ***underpinned by the precautionary principle[1], whereby it is up to manufacturers, importers and downstream users*** to ensure ***that they manufacture, place*** on the market***, import and use only such substances that, when used in accordance with the requirements, do not adversely affect human health or the environment. It includes the obligation to describe, document and notify the risks associated with the production and use of any substance in an appropriate, transparent fashion.*** ***[1] As set out in the Communication from the Commission on the precautionary principle (COM(2000) 1 final)***

Justification

Linguistic improvement of original Amendment 17by introducing the notion of 'use in accordance with the requirements' as an established legal concept. The word 'sale' is deleted as the term 'use' already covers its essential content.

Amendment 26
Article 1, paragraph 3

3. This Regulation ***is based*** on ***the principle that it is up*** to ***manufacturers, importers and downstream users to ensure that they***	3. This Regulation ***lays down provisions*** on ***substances, preparations and articles within the meaning of Article 3(1). These***

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[1].***	***provisions shall apply*** to ***the*** manufacture, import***, placing on the market*** or use ***of*** such substances ***on their own, in preparations*** **or** ***in articles, if so stated***.

[1] As set out in the Communication from the Commission on the precautionary principle, COM(2000) 1 final

Amendment 27
Article 2, Paragraph 1, Point c, c a (new) and c b (new)

(c) non-isolated intermediates**.**	(c) non-isolated intermediates***;***
	(ca) the transport of substances and preparations by rail, road, inland waterway, sea or air;
	(cb) substances, preparations or articles that are waste as defined in Directive 75/442/EEC.

Justification

This amendment serves clarity and improved readability of REACH. All exemptions from the scope of REACH should be collected in Article 2 so that enterprises who will not have to apply REACH do not have to study the whole proposal.

In order to avoid duplication of work for enterprises and authorities, all those substances used in products governed by specific Community legislation should be exempt from the scope of the titles on Registration, Evaluation, Authorisation, Data Sharing, Information in the supply chain and Downstream user obligations.

A general reference should ensure that that all existing legislation on workplace prevails.

The compromise amendments to Recital 100a and Articles 2, 4, 4a, 7, 8 have to be read together.

Amendment 28
Article 2, Paragraph 2

2. ***This Regulation shall apply without prejudice to:***	2. ***The provisions of the Titles of this Regulation on Registration, Evaluation, Data sharing, Information in the supply chain, Downstream users and Authorisation shall not apply to the extent***

	that a substance is destined for use:
(a) Council Directive 89/391/EEC;	***(a) in medicinal products for human or veterinary use within the meaning of Council Regulation (EC) No 726/2004, Directive 2001/82/EC of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council;***
(b) Directive 90/394/EEC;	***(b) in food within the meaning of Regulation (EC) No 178/2002, including food additives within the meaning of Council Directive 89/107/EEC and flavourings/ flavouring substances within the meaning of Council Directive 88/388/EEC and Commission Decision 1999/217/EC;***
(c) Council Directive 98/24/EC;	***(c) in animal feed within the meaning of Regulation (EC) No. 178/2002, including feed additives within the scope of Regulation (EC) No 1831/2003 on additives for use in animal nutrition, and animal feed within the scope of Council Directive 84/471/EEC;***
(d) Community legislation on the carriage of dangerous substances and dangerous substances in preparation by rail, road, inland waterway, sea or air.	***(d) in medical devices within the scope of Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC;***
	(e) in materials which come into contact with foodstuffs within the meaning of Regulation (EC) No. 1935/2004;
	(f) in plant protection products within the meaning of Council Directive 91/414/EEC;
	(g) in biocidal products within the meaning of Council Directive 98/8/EC;
	(h) in active implantable medical devices within the meaning of Council Directive 90/385/EEC and Council Directive 93/68/EEC;
	(i) in in-vitro-diagnostic medical devices within the meaning of Directive 98/79/EC;
	(j) in batteries and accumulators within the meaning of Directive 91/157/EC (or … No. of the new battery directive).
	The list of excluded substances may be

revised, on the basis of a recommendation by the Agency or a Commission initiative, by a Commission decision adopted in accordance with the procedure set out in Article 130(3).

Justification

This amendment serves clarity and improved readability of REACH. All exemptions from the scope of REACH should be collected in Article 2 so that enterprises who will not have to apply REACH do not have to study the whole proposal.

In order to avoid duplication of work for enterprises and authorities, all those substances used in products governed by specific Community legislation should be exempt from the scope of the titles on Registration, Evaluation, Authorisation, Data Sharing, Information in the supply chain and Downstream user obligations.

A general reference should ensure that that all existing legislation on workplace prevails.

The compromise amendments to Recital 100a and Articles 2, 4, 4a, 7, 8 have to be read together.

Amendment 29
Article 2, Paragraph 2 a (new) and 2 b (new)

(2a) This Regulation shall apply without prejudice to Community workplace legislation.

(2b) The present Regulation is without prejudice to the prohibitions and restrictions laid down in Council Directive 76/768, as amended, concerning:

(a) the testing on animals of the final formulation of cosmetic products or some or all of the ingredients thereof; and

(b) the marketing of cosmetic products some or all of the ingredients of which, or the final formulation thereof, have been tested on animals.

To the extent that substances used as cosmetics ingredients are covered by this Regulation, no testing on animals shall be permitted for the purposes of any assessment required by this Regulation with regard to such substances other than as permitted by Council Directive

76/768/EEC.

Justification

This amendment serves clarity and improved readability of REACH. All exemptions from the scope of REACH should be collected in Article 2 so that enterprises who will not have to apply REACH do not have to study the whole proposal.

In order to avoid duplication of work for enterprises and authorities, all those substances used in products governed by specific Community legislation should be exempt from the scope of the titles on Registration, Evaluation, Authorisation, Data Sharing, Information in the supply chain and Downstream user obligations.

A general reference should ensure that that all existing legislation on workplace prevails.

The compromise amendments to Recital 100a and Articles 2, 4, 4a, 7, 8 have to be read together.

Amendment 30
Article 3, Paragraph 1 a (new)

(1a) A botanically-derived substance means a complex substance obtained by subjecting a plant or its parts to a physical treatment such as extraction, distillation, expression, fractionation, purification, concentration or to fermentation, the composition of which varies depending on the genus , species, growing conditions of its source and the process used for its treatment.

Justification

The introduction of a specific definition for natural substances derived from botanicals under REACH is necessary to clarify the scope of the exemption provided under Annex III for natural substances and ensure legal certainty in the implementation of REACH provisions.

This category of natural substances encompasses a wide diversity of substances, which are not well-defined chemical elements within the meaning of the definition of 'substances' included in the Commission proposal. Botanically-derived substances should therefore be distinguished from other substances covered by REACH.

Amendment 31
Article 3, Paragraph 2

2. *Preparation* means a mixture or solution composed of two or more substances;	2. *Preparation* means a mixture or solution composed of two or more substances; ***metallic alloys are special types of preparations.***
	Where there is reason to suspect the presence of properties other than those that can be assumed on the basis of the individual components, it must be possible to subject metal alloys to an evaluation on the basis of their own specific intrinsic properties.

Justification

Alloys are preparations and therefore do not have to be registered as such, though their individual components (metals) do. However, alloys may have properties other than may be apparent from their individual component parts since the substances contained therein (metals) melt together to form a new, no longer soluble crystal lattice. There should therefore be a possibility of evaluating the alloy as such if there is reason to suspect that the alloy displays properties other than those an examination of the individual components makes apparent.

Amendment 32
Article 3, Paragraph 3

(3) Article means an object composed of one or more substances or preparations which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does;	(3) Article means an object composed of one or more substances or preparations which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does; ***Complex products composed of more than one article are a collection of articles. Duties concerning articles arising from this Regulation apply to articles when they are sold between separate legal entities.***

Justification

Clarity is needed on what constitutes an article, in particular as far as complex products that are in fact a collection of articles. The proposed clarification would ensure that measures are taken as early as possible in the supply chain to address the duties of REACH, and prevent that obligations are pushed downstream.

Amendment 33
Article 3, paragraph 4, points (a) and (b)

4. *Polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. ***A polymer comprises the following:***	4. *Polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units ***and comprising a simple weight majority of molecules containing at least three monomer units which are bound to at least one other monomer unit or other reactant, with the substance consisting of less than a simple weight majority of molecules of the same molecular weight***. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.
(a) a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;	
(b) less than a simple weight majority of molecules of the same molecular weight.	

Justification

The above definition of a polymer is essentially the OECD definition, which also appears in Directive 92/32/EEC, is regarded as the 'standard definition' and should therefore be retained.

Amendment 34
Article 3, paragraph 12 a (new)

	12a. Categories of use mean the classification pursuant to Annex IV Section 5 of uses differentiated as follows: industrial use, professional use and consumer use;

Justification

The concept of categories of use and exposure categories will make the data requirements more systematic and focused, and facilitate communication along the product chain. Instead of looking at product groups, typical types of exposure undergone by humans and the environment will be identified and classified, without reference to the use of a substance. A detailed exposition can be found in the amendments relating to Annex Iba (new).

Amendment 35
Article 3, paragraph 12 b (new)

12b. Exposure categories mean the classification of exposure according to the relevant types of absorption in humans (oral, dermal or by inhalation), the ways in which substances get into the environment (air, water or soil) and the duration of exposure (once or short-term, occasional, repeated or long-term);

Justification

The concept of categories of use and exposure categories will make the data requirements more systematic and focused, and facilitate communication along the product chain. See comprehensive justification relating to paragraph 12a.

Amendment 36
Article 3, paragraph 12 c (new)

12c. Exposure scenario means the description of the practical measures to protect humans and the environment and of the specific conditions for the manufacture and use of a substance throughout its life;

Justification

Unlike categories of use and exposure categories, an exposure scenario describes the specific individual conditions for use of a substance, and in particular the practical protective measures.

Amendment 37
Article 3, paragraph 14, introductory part

14. *Intermediate* means a substance that is ***solely*** manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter called *synthesis*):	14. *Intermediate* means a substance ***or preparation*** that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter called *synthesis*):

Justification

The derogation should also apply to substances which are not only used as intermediates.

Amendment 38
Article 3, paragraph 14 a (new)

14a. Chemically unmodified substance means a substance the chemical structure of which has not been modified even if it has undergone a chemical process, e.g. if a substance has been chemically treated to remove impurities;

Justification

The proposed Regulation exempts from registration substances which are natural, if they have not been chemically modified during their manufacture. Even if cellulose fibres are produced in a chemical process, their structure is not modified. Consequently, all forms and processes used to produce cellulose fibres should be covered by this exemption.

Amendment 39
Article 3, Paragraph 20

20. *Phase-in substance* means a substance which, ***over the 15 years preceding the entry into force of this Regulation,*** meets at least one of the following criteria:	20. *Phase-in substance* means a substance which meets at least one of the following criteria:
(a) ***It was manufactured in or imported into the Community, or the countries acceding to the European Union on 1 May 2004, by a manufacturer or importer and*** is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);	(a) is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
(b) **It** was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer;	(b) was manufactured in the Community, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer ***at least once in the 15 years before the entry into force of the Regulation*****;**
(c) ***It*** was placed on the market in the Community, or in the countries acceding to the European Union on 1 May 2004, and between 18 September 1981 and 31 October 1993 inclusive it was also placed on the market by the manufacturer or importer and was considered as having been notified in accordance with the first indent	(c) ***it*** was placed on the market in the Community, or in the countries acceding to the European Union on 1 May 2004, and between 18 September 1981 and 31 October 1993 inclusive it was also placed on the market by the manufacturer or importer and was considered as having been notified in accordance with the first indent

of Article 8 (1) of Directive 67/548/EEC, as amended by Directive 79/831/EEC, but does not meet the definition of a polymer set out in Directive 67/548/EEC, as amended by Directive 92/32/EEC;	of Article 8 (1) of Directive 67/548/EEC, as amended by Directive 79/831/EEC, but does not meet the definition of a polymer set out in Directive 67/548/EEC, as amended by Directive 92/32/EEC;

Justification

All substances in EINECS should be regarded as potential phase-in substances. There is no need for a bureaucratic proof or confirmation procedure that the substance was manufactured or imported within 15 years in the EU.

Manufactures and importers can maintain the phase-in status and therefore make use of the transitional phase-in periods if they notify the substance in accordance with Article 22a new to the register of substances.

Amendment 40
Article 3, Paragraph 22

(22) Product and process orientated research and development means any scientific development related to product development, the further development of a substance in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;	(22) Product and process orientated research and development means any scientific development related to product development, the further development of a substance***, on its own, in preparations or in articles,*** in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;

Justification

This amendment clarifies that product and process related research and development can cover substances on their own, in preparations and in articles. linked to amendments 13, 14 and 15.

Amendment 41
Article 3, paragraph 23

23. *Scientific research and development* means any scientific experimentation, analysis or chemical research carried out under controlled conditions ***in a volume less than 1 tonne per year***;	23. *Scientific research and development* means any scientific experimentation, analysis or chemical research carried out under controlled conditions;

Justification

The 1-tonne limit is an unwarranted restriction on scientific and research freedom.

Amendment 42
Article 3, Paragraph 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 and that is covered in the safety data sheet communicated to the downstream user concerned;	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 covered in the safety data sheet communicated to the downstream user concerned; ***the identified use is stated by indicating the category of use and exposure category***

Justification

Rewording of original Amendment 34. 'Identified use' is stated solely by indicating the category of use and exposure category. This is particularly important for SMEs as it allows for simpler management of the system and manufacturing and commercial secrets to be safeguarded.

Amendment 43
Article 3, paragraph 29 a (new)

	29a. Core information means basic data for prioritising substances on the basis of the inherent properties of, exposure to and use of substances as specified in Annex Ic (Categories of use), Annex Id (Exposure), Annex IV and Annex V;

Justification

As part of the establishment of the inventory of substances (see Article 3(20), as a second stage firms will also submit core information (see Article 22c). This will include the most important information about the properties of, exposure to and use of substances.

Amendment 44
Article 3, paragraph 29 a (new)

29a. Small and medium-sized enterprises means such enterprises as defined in Recommendation 2003/361/EC of 6 May 2003.

Justification

In the interests of correct application of the rules, a definition of small and medium-sized enterprises needs to be included, since they are particularly vulnerable participants in the procedure. This amendment is linked to the other amendments to the articles under Title I: General Issues.

Amendment 45
Article 3, paragraph 29 b (new)

29b. Register of substances means the register, to be operated by the Agency, containing the information relating to the substances notified during pre-registration;

Justification

Amendment follows from Article 3(20). Definition provides the basis for Article 22c.

Amendment 46
Article 3, paragraph 29 c (new)

29c. Metallic alloy means a metallic material, homogeneous on a macroscopic scale, consisting of two or more chemical elements so combined that they cannot be separated by mechanical means.

Justification

This definition corresponds to the UN Globally Harmonized System for Chemical Classification and Labelling (GHS) and also to the Preparations Directive (Directive 1999/45/EC). Inorganic metal components and metals are 'substances' pursuant to Article 3, but there is no definition of alloys.

Amendment 47
Article 4, Paragraph 1

(1) The provisions of this Title shall not apply to the extent that a substance is used:	***deleted***
(a) in medicinal products for human or veterinary use within the scope of Regulation (EEC) No 2309/93, Directive 2001/82/EC of the European Parliament and of the Council[1] and Directive 2001/83/EC of the European Parliament and of the Council[2];	
(b) as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC[3];	
(c) as a flavouring in foodstuffs within the scope of Commission Decision 1999/217/EC[4];	
(d) as an additive in feedingstuffs within the scope of Council Directive 70/524/EEC[5];	
(e) in animal nutrition within the scope of Council Directive 82/471/EEC[6].	
[1] OJ L 311, 28.11.2001, p. 1.	
[2] OJ L 311, 28.11.2001, p. 67.	
[3] OJ L 40, 11.2.1989, p. 27.	
[4] OJ L 84, 27.3.1999, p. 1.	
[5] OJ L 270, 14.12.1970, p. 1.	
[6] OJ L 213, 21.7.1982, p. 8.	

Justification

This amendment serves clarity and improved readability of REACH. As a consequence to moving exemptions to Articles 2, Articles 4 needs to be modified.

Some substances which are a result of specific recycling processes should also be exempt from the obligation to register provided that the enterprise performing the recycling process has been provided with information on the substance.

The compromise amendments to Recital 100a and Articles 2, 4, 4a, 7, 8 have to be read together.

Amendment 48

Article 4, Paragraph 2, Point c a (new)

(ca) substances on their own or in preparations, which have been registered in accordance with this Title by a manufacturer or importer, and which are recycled in the Community by another manufacturer or importer who shows that:

i) the substance being the result of the recycling process is the same as the already registered substance; and

ii) he has been provided with the information in accordance with Articles 29 and 30 relating to the registered substance.

Justification

This amendment serves clarity and improved readability of REACH. As a consequence to moving exemptions to Articles 2, Articles 4 needs to be modified.

Some substances which are a result of specific recycling processes should also be exempt from the obligation to register provided that the enterprise performing the recycling process has been provided with information on the substance.

The compromise amendments to Recital 100a and Articles 2, 4, 4a, 7, 8 have to be read together.

Amendment 49
Article 4 a (new)

(4a) Exemptions from the obligation to register for product and process orientated research and development (PPORD)

(1) A substance manufactured in the Community, or imported for the purposes of product and process orientated research and development shall be exempt from the obligation to register set out in Articles 5, 6, 15, 16, and 19 for a period of five years, provided the manufacturer or importer notifies the Agency of the following information in the format specified by the Agency in accordance with Article 108:

(a) the identity of the manufacturer or importer;

(b) the identity of the substance;

(c) the classification of the substance, if any;

(d) the estimated quantity; and

(e) the list of his customers, if any.

Such a substance shall not be made available to the general public at any time either on its own or in a preparation or in an article. The staff of the customer(s) or of the notifier shall handle the substance in reasonably controlled conditions. Remaining quantities of the substance shall be re-collected for disposal after the exemption period or at the end of the research activities, whatever is earlier.

(2) The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to the manufacturer or importer concerned and shall forward the information notified and the number and date to the competent authority of each Member State in which the substance is manufactured, imported or used for the purpose of the product and process orientated research and development.

(3) The Agency may extend the five-year exemption period by a further maximum of 10 years upon request of the manufacturer or importer, if he can demonstrate that such an extension is justified by the research and development programme. The notifier may bring an appeal against any negative decision in this respect according to Article 87 to 89.

(4) The Agency and the competent authorities of the respective Member State(s) shall always keep confidential the information submitted in accordance with paragraph 1.

Justification

This amendment encourages product and process oriented R&D by simplifying the

requirements set out in the Commission proposal and by opening up opportunities for downstream users while preserving the possibility for authorities to intervene. It should be sufficient to know where the PPORD takes place so that, in cases of concern, the authorities know whom to address and thus are able to act quickly.

Amendment 50
Article 5, paragraph 1 a (new)

1a. Substances in preparations shall be exempted from registration as specified in paragraph 1 if the concentration of a substance in the preparation is less than the lowest concentration specified in one of the following provisions:

(a) the applicable concentrations specified in the table in Article 3(3) of Directive 1999/45/EC;

(b) the concentration limit values listed in Annex I to Directive 67/548/EEC;

(c) 0.1 %, if the substance meets the criteria in Annex XII.

Justification

Takes over the limits laid down in Article 13 for substances and preparations. Even the smallest traces would have to be covered if there were no limits to the concentrations to be considered. This is unreasonable.

Amendment 51
Article 5, Paragraph 2

2. A submission for registration shall be accompanied by the fee as set by the Agency.	2. A submission for registration shall be accompanied by the fee as set by the Agency. ***A fee need not be paid for a registration for a substance in a quantity between 1 and 10 tonnes for which the hazard dossier includes all information specified in Annex V; a fee need not be paid, either, for a registration for a substance in a quantity between 10 and 100 tonnes for which the hazard dossier includes all information specified in Annexes V and VI.***

Justification

This amendment shall encourage the submission of complete data for substances between 1 and 100 tonnes, where more information than in the Commission proposal will be generated for substances between 1 and 10 tonnes for the benefit of health and environment while at the same time reducing the overall costs on SMEs and making it more proportionate.

These two elements in the registration dossier will:

- firstly, guide companies to use their available data, review it and draw adequate conclusions for risk management resulting in better quality safety data sheets and safe use for substances classified as dangerous.

- secondly, assist the Agency in performing a screening to identify substances that could pose a high risk for which more information will have to be generated.

Amendment 52
Article 5, paragraph 3, introductory part

3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the ***non-registered*** monomer substance(s) or other non-registered substance(s) if both the following conditions are met:	3. Any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) ***which has/have not been registered by an actor up the supply chain*** or other non-registered substance(s) if both the following conditions are met***, provided that the monomers arise during synthesis and cannot be isolated***:

Justification

Some monomers arise during the production process and immediately react further. Registration is therefore impossible at a defensible cost.

However, if a monomer or other non-registered substance has already been registered by the manufacturer or by his designated representative, the polymer manufacturer may use this registration, provided that the registrant indicates the use of the substance during the manufacture of the polymer.

Amendment 53
Article 5, Paragraph 3, Point b, Subparagraph 1 a (new)

	A notification for such monomer/substance shall include the following information in the format specified by the Agency in accordance with Article 108 :

(i) the identity and contact details of the producer or importer;
(ii) the identity of the monomer/substance as specified in section 2 of Annex IV;
(iii) the classification of the substance;

(iv) a brief description of the use of the polymer;

Justification

Importers/manufacturers of polymers do not place the monomers or other substances contained in polymers on the EU market. This fact distinguishes them from manufacturers and importers of monomers/substances which do place monomers/substances on the EU market. It is also accepted that polymers, by their nature, pose a limited risk to human health and the environment.

Amendment 54
Article 5, Paragraph 3, Point (b a) (new)

(ba) A registration under this title shall be made for the non-registered monomer substance manufactured or imported in quantities of more than 1000 tonnes per year. This registration shall include the information specified in Annex V in addition to the information required above.

Justification

There seems to be no reason to put monomers/substances in polymers through full registration under REACH and it is therefore appropriate for such monomers/substances to be subject to lesser notification and, where applicable, registration requirements.

Amendment 55
Article 5, paragraph 4

4. A submission for registration shall be accompanied by the fee as set by the Agency.	4. A submission for registration shall be accompanied by the fee as set by the Agency. ***The fee should be commensurate with the type of registration dossier concerned.***

Justification

To make matters easier for SMEs, the registration fee set by the agency should be commensurate with the information supplied for the purpose of registering the substance. This amendment is linked to the other amendments tabled to the articles set out in Title II: Registration of substances.

Amendment 56
Article 6, Paragraph 1, Point a

(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;***	(a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;

Justification

Reference to article type should be deleted. Reference to Directive 67/548/EEC is taken up in Art. 6(1a) new.

Amendment 57
Article 6, Paragraph 1, Point b

(b) the substance ***meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC***;	b) the ***concentration of the*** substance ***exceeds 0.1% by weight in each article*****;. *In determining the concentration of substances in articles, the component parts of a compound article shall be examined separately. The same applies to coatings applied to surfaces of an article. Detailed provisions shall be laid down in guidelines;***

Justification

Reference to article type should be deleted. Reference to Directive 67/548/EEC is taken up in Art. 6(1a) new.

Amendment 58
Article 6, Paragraph 1, Point c a (new)

(ca) the substance is not excluded from the registration requirement.

Justification

Reference to article type should be deleted. Reference to Directive 67/548/EEC is taken up in Art. 6(1a) new.

Amendment 59
Article 6, Paragraph 1, Point (c a) (new)

(ca) the substance has not been registered for that use by an actor up the supply chain.

Amendment 60
Article 6, Paragraph 1 a (new)

1a. A registration pursuant to paragraph 1 shall not be required for a substance which is present in a preparation at a concentration lower than the lowest defined in any of the following provisions:

a) the applicable concentrations given in the table in Article 3(3) of Directive 1999/45/EC;

b) the concentration limit values given in Annex I to Directive 67/548/EEC;

Justification

Introduction of cut-off criteria.

Amendment 61
Article 6, Paragraph 1 a (new)

(1a) The Commission shall adopt Guidelines clarifying the coverage of 'article type' at the latest 3 months after the

deadline specified in Article 21(3).

Amendment 62
Article 6, Paragraph 2, 3 and 4

(2) Any producer or importer of articles shall notify the Agency of any substance contained in those articles in accordance with paragraph 3, if all the following conditions are met:	***deleted***
(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 it is made known to the producer or importer, 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;	
(d) the quantity of the substance released may adversely affect human health or the environment.	
(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:	
(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.

(4) The Agency may take decisions requiring producers or importers of articles to register, in accordance with this Title, any substance contained in those articles and notified in accordance with paragraph 3.

Justification

Paragraphs 2 to 4 are not practicable and difficult to enforce. Many definitions are missing or too vague (e.g. 'article type', 'is made known' or 'likely to be released'). Furthermore, the provisions should better take into account considerations under international trade agreements.

Amendment 63
Article 6, Paragraph 5, 6 and 7

(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.	(5) Paragraph 1 shall not apply to substances that have already been registered for that use by an actor up the supply chain.
(6) Paragraphs 1 ***to 4*** shall apply ***3*** months after the deadline specified in Article 21(3).	(6) Paragraph 1 shall apply ***6*** months after the deadline specified in Article 21(3).
(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).	(7) Any measures for the implementation of paragraphs 1 ***and 1bis*** shall be adopted in accordance with the procedure referred to in Article 130(3).

Justification

Paragraphs 2 to 4 are not practicable and difficult to enforce. Many definitions are missing or too vague (e.g. 'article type', 'is made known' or 'likely to be released'). Furthermore, the provisions should better take into account considerations under international trade agreements.

Amendment 64
Article 6 b (new), title

Article 6b

Transfer and splitting of registrations and 'collective registrations'

Amendment 65
Article 6 b (new), paragraph 1

1. The legal entitlement acquired through registration shall be both transferable and divisible. The party acquiring such an entitlement shall take over the rights and obligations of the original registrant. Where a registration is split, the Agency shall assign a new registration number to the new holder.

Justification

If a registrant no longer wishes to make use of his registration it must be possible for him to transfer the rights arising from the registration. The divisibility of rights arising from a registration is necessary in cases in which only part of a firm is transferred to a new owner. Since each manufacturer or importer must have a registration number as evidence of registration status, in such cases the Agency must assign a new registration number to the new owner.

Amendment 66
Article 6 b (new), paragraph 2

2. Where a manufacturer is a subsidiary of another legal person (termed the 'parent company'), the parent company may undertake and maintain a registration on behalf of the subsidiary. Conversely, a subsidiary may also undertake and maintain a registration for its parent company or for other subsidiaries. In such cases registration shall be required once only. The legal person designated for collective registration purposes shall be responsible for performance of duties under this Regulation.

Amendment 67
Article 6 b (new), paragraph 3

3. Paragraph 2 shall also apply where the registered office of the parent company or the subsidiary is not located in the European Union. The legal person designated for collective registration

	purposes must have his registered office in the Union.

Justification

Within conglomerates products are delivered from changing production plants to downstream users within the European Union who may belong to different subsidiaries. The delivery of products within a conglomerate is often coordinated by a unit which may be part of either the parent company or a subsidiary. The proposed group registration would be an appropriate way of reducing costs and bureaucracy.

Amendment 68
Article 7

(1) Articles 5 and 19 shall not apply for a period of five years to a substance manufactured in the Community or imported for the purposes of product and process orientated research and development with a number of listed customers and in a quantity which are limited to the purpose of product and process orientated research and development.	***deleted***
(2) For the purpose of paragraph 1, the manufacturer or importer shall notify the Agency of the following information in the format specified by the Agency in accordance with Article 108:	
(a) the identity of the manufacturer or importer;	
(b) the identity of the substance;	
(c) the classification of the substance, if any;	
(d) the estimated quantity;	
(e) the list of customers referred to in paragraph 1; and	
(f) sufficient information on the research and development programme to enable the Agency to take informed decisions under paragraphs 4 and 7.	
The period set out in paragraph 1 shall begin at receipt of the notification at the Agency.	

(3) The Agency shall assign a number to the notification and a notification date, which shall be the date of receipt of the notification at the Agency, and shall forthwith communicate that number and date to the manufacturer or importer concerned.

(4) The Agency shall check the completeness of the information supplied by the notifier. It may decide to impose conditions with the aim of ensuring that the substance or the preparation or article in which the substance is incorporated will be handled only by staff of listed customers as referred to in paragraph 2(e) in reasonably controlled conditions and will not be made available to the general public at any time either on its own or in a preparation or article and that remaining quantities will be re-collected for disposal after the exemption period.

(5) In the absence of any indication to the contrary, the manufacturer or importer of the substance may manufacture or import the substance not earlier than four weeks after the notification.

(6) The manufacturer or importer shall comply with any conditions imposed by the Agency in accordance with paragraph 4.

(7) The Agency may decide to extend the five-year exemption period by a further maximum of five years or, in the case of substances to be used exclusively in the development of medicinal products for human or veterinary use, for a further maximum of 10 years, upon request if the manufacturer or importer can demonstrate that such an extension is justified by the research and development programme.

(8) The Agency shall forthwith communicate any draft decisions to the competent authorities of each Member State in which the manufacture, import or product and process orientated research takes place. When taking decisions as provided for in paragraphs 4 and 7, the Agency shall take into account any

comments made by such competent authorities.

(9) The Agency and the competent authorities of the respective Member States shall always keep confidential the information submitted in accordance with paragraphs 1 to 8.

(10) An appeal may be brought, in accordance with Articles 87, 88 and 89, against Agency decisions under paragraphs 4 and 7.

Justification

This amendment encourages product and process oriented R&D by simplifying the requirements set out in the Commission proposal and by opening up opportunities for downstream users while preserving the possibility for authorities to intervene. It should be sufficient to know where the PPORD takes place so that, in cases of concern, the authorities know whom to address and thus are able to act quickly.

The provisions on PPORD should be placed at the beginning of Title II as a new Article 4a as they contain a general exemption from the duty to register. Article 7, as a consequence, has to be deleted.

Amendment 69
Article 8

Substances in plant protection and biocidal products

deleted

(1) Active substances manufactured or imported for use in plant protection products only and included either in Annex I to Council Directive 91/414/EEC or in Commission Regulation (EEC) No 3600/92, Commission Regulation (EC) No 703/2001, Commission Regulation (EC) No 1490/2002, Commission Decision 2003/565/EC and for any substance for which a Commission Decision on the completeness of the dossier has been taken pursuant to Article 6 of Directive 91/414/EEC shall be regarded as registered for manufacture or import for the uses covered by such an inclusion and therefore as fulfilling the requirements of this

Chapter and of Article 20.

(2) Active substances manufactured or imported for use in biocidal products only and included either in Annexes I, IA or IB to Directive 98/8/EC of the European Parliament and of the Council or in Commission Regulation (EC) No …/…{Second Review Regulation}, until the date of the decision referred to in the second subparagraph of Article 16(2) of Directive 98/8/EC, shall be regarded as registered for manufacture or import for the uses covered by such an inclusion and therefore as fulfilling the requirements of this Chapter and of Article 20.

Justification

Follow up amendment as exemption has been moved to Art. 2.

Amendment 70
Article 9

A registration required ***by*** Article 5 or ***by*** Article 6***(1) or (4)*** shall include all the following information in the format specified by the Agency in accordance with Article 108:	A registration ***dossier*** required ***to be submitted to the Agency according to*** Article***s*** 5 or 6 shall include all the following information in the format specified by the Agency in accordance with Article 108:
(a) ***a technical*** dossier including:	(a) an ***individual*** dossier including:
i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex IV;	i) the identity of the manufacturer(s) or importer(s) as specified in section 1 of Annex VI;
ii) the identity of the substance(s) as specified in section 2 of Annex IV;	ii) the identity of the substance(s) aspecified in section 2 of Annex VI;
iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex IV; this information shall ***represent*** all the registrant's identified use(s);	iii) information on the manufacture and use(s) of the substance as specified in section 3 of Annex IV; this information shall ***include*** all the registrant's identified use(s) ***and shall in particular point out the uses he advises against;***
iv) ***the classification and labelling of the substance as specified in section 4 of Annex IV;***	iv) ***information on use and exposure categories as specified in Annex IV section 5;***
v) guidance on safe use of the substance as	

specified in Section 5 of Annex IV;	
vi) summaries of the information derived from the application of Annexes V to IX;	
vii) robust study summaries of the information derived from the application of Annexes V to IX, if required under Annex I;	
viii) a statement as to whether or not information has been generated by testing on vertebrate animals;	
ix) proposals for testing where required by the application of Annexes V to IX;	
x) a declaration as to whether he agrees that his summaries and robust study summaries of the information derived from the application of Annexes V to VIII with regard to tests not involving vertebrate animals may be shared against payment with subsequent registrants;	
b) ***a chemical safety report when required under Article 13.***	b) ***a hazard dossier including:***
	i) the studies or the robust summaries of the information derived from the application of Articles 11 to 13;
	ii) the studies or summaries of any other information derived from the application of Articles 11 and 12;
	iii) proposals for testing where required by the application of Articles 11 to 13;
	iv) a statement as to whether or not information has been generated by testing on vertebrate animals;
	v) a declaration as to whether studies , study summaries or robust study summaries of the information with regard to tests not involving vertebrate animals may be shared against payment with subsequent registrants within the 15 years after its submission;
	vi) confirmation that the registrant is the owner of the original studies submitted or from which study summaries or robust study summaries are derived and submitted,

or the written consent of the owner of the original studies to refer to them (letter of access);

(c) the hazard classification and labelling of the substance as specified in section 4 of Annex IV;

(d) for substances in quantities of 10 tonnes or more per year a chemical safety report in accordance with Article 13*;*

(e) the safety data sheet, if required in accordance with Article 29 or, otherwise, guidance on safe use as set out in Annex Ic (new); including an indication of which information the registrant considers as confidential.

Justification

This amendment sets out the information to be submitted:

1.The individual dossier is not new compared to the Commission proposal, it only integrates information on the identity of the enterprise, the substances and the uses.

Some basic exposure information will need to be submitted which will help manufacturers and importers of substances, in particular in quantities of 1 to 100 tonnes, to develop the safety data sheet/guidance on safe use.

2. The hazard dossier is not new compared to the Commission proposal and its content is specified in Article 11 in connection with the testing Annexes.

3. The classification and labelling for a dangerous substance will as, in the Commission proposal, be a separate item of the registration dossier.

Amendment 71
Article 9, Point (b a) (new)

(ba) For purposes of compliance with paragraph (a), data sets for a chemical substance or a group of chemical substances submitted under the Organisation for Economic Co-operation and Development (OECD) High Production Volume (HPV) Chemicals Programme, the International Council of Chemical Associations (ICCA) HPV

Initiative, or the U.S. Environmental Protection Agency (EPA) HPV Challenge shall be presumed to meet the requirements of subparagraphs (a)(vi)-(x).

Justification

The OECD HPV Chemicals Programme provides the basis for the successful collection and assessment of data concerning the public health and environmental effects of high volume substances produced or imported by OECD members. The use of data developed under this system is consonant with the registration requirements of REACH , which should prevent unnecessary duplicative and costly development of data, particularly where it would result in testing involving vertebrate animals, and to speed the ability of the information to be disseminated to the public.

Amendment 72
Article 10, title

Joint submission of data by members of consortia	***Pre-registration and formation of consortia on a voluntary basis***

Justification

The formation of consortia should be encouraged by giving legal force to a so-called 'pre-registration' phase. Members of a consortium should pay an equitable share of the registration fee.

Amendment 73
Article 10, paragraph -1 (new)

-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, it is preferable for only one manufacturer or importer to carry out the registration.

In providing the information pursuant to Article 9(a)(i) the other manufacturers and/or importers may refer to all or part of that registration if the written consent of the manufacturer/importer who carried out the registration is provided. The consent shall be granted in so far as Article 25 is relevant.

	Information pursuant to Article 9(a)(vi) shall be submitted separately only if such information is already available or if there are other substantial grounds militating against a reference to the registration which has already been carried out.
	In the case of a full reference, at the request of the manufacturers/importers making that reference the Agency shall assign the same registration number.
	In the case of a partial reference, the missing information shall be submitted separately.

Justification

This entitles manufacturers/importers to use references to other registrations so as to dispense with having to submit their own documents. This will ease the burden on SMEs, in particular, who will be able to dispense with the time-consuming preparation of dossiers.

The requirement to obtain consent to a reference, by citing Article 25, will ensure that vertebrate testing data are not repeated and that such data are submitted only once.

This provision effectively implements the 'one substance - one registration' principle (up to and including the same registration number).

Amendment 74
Article 10, paragraph 1

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.***	1. ***Alternatively,*** two or more manufacturers ***in the Community or*** two or more importers may form a consortium for the purposes of registration. Parts of the registration shall be submitted by one manufacturer or importer ***or third party*** acting, with their agreement, on behalf of other manufacturers and/or importers in ***in the following way:***

Justification

Guidelines are needed to support firms in setting up and in operating in consortia, and also to forestall possible breaches of competition law.

Amendment 75
Article 10, paragraph 1, second subparagraph

Each member of the consortium shall submit separately the information specified in Article 9(a)(i), (ii) and (iii), and (viii).	***Deleted***

Amendment 76
Article 10, paragraph 1, third subparagraph

The one manufacturer or importer submitting on behalf of the other members of the consortium shall submit the information specified in Article 9(a)(iv), (vi), (vii) and (ix).	The one manufacturer or importer ***or third party*** submitting on behalf of the other members of the consortium shall submit the information specified in Article 9(a)(iv), (vi), (vii) and (ix). ***Each consortium may submit the information pursuant to Article 9(a)(i), (ii) and (iii) jointly.***

Justification

Where information is submitted jointly it must be sufficient for a manufacturer or importer who is acting on behalf of the other members of the consortium to submit a statement pursuant to Article 9(a)(viii).

Amendment 77
Article 10, Paragraph 1, fourth subparagraph

The members of the consortium may decide themselves whether to submit the information specified in Article 9(a)(v) and (b) separately or whether the one manufacturer or importer is to submit this information on behalf of the others.	The members of the consortium may decide themselves whether they submit the information specified in Article 9 (a) (v) and (b) separately or whether the one manufacturer or importer ***or third party*** is to submit this information ***in full or in part*** on behalf of the others.

Amendment 78
Article 10, Paragraph 1, Subparagraph 4 a (new)

	In order to support manufacturers or importers who belong to consortia, the

Commission shall draft guidelines for compliance with competition law

Justification

Guidelines are needed in order to facilitate the formation of consortia by manufacturers and importers and their work. Such guidelines are also essential as an incentive to form consortia, otherwise the situation would be extremely uncertain in legal terms.

Amendment 79
Article 10, paragraph 1 a (new)

1a. The Agency shall publish, within three months of the end of the pre-registration phase, the list of substances declared pursuant to paragraph 1.

Justification

The formation of consortia should be encouraged by giving legal force to a so-called 'pre-registration' phase. Members of a consortium should pay an equitable share of the registration fee.

Amendment 80
Article 10, paragraph 1 b (new)

1b. Producers and importers of the same substance shall, if they so wish, form a consortium.

The one manufacturer or importer acting on behalf of the other members of the consortium shall submit the information specified in Article 9(a)(iv), (vi), (vii) and (ix).

The members of the consortium may decide themselves whether to submit the information specified in Article 9(a)(v) and (b) separately or whether the one manufacturer or importer is to submit this information on behalf of the others.

Justification

The formation of consortia should be encouraged by giving legal force to a so-called 'pre-registration' phase. Members of a consortium should pay an equitable share of the registration fee.

Amendment 81
Article 10, Paragraph 2

(2) Each registrant who is a member of a consortium shall pay only one-third of the fee for registration.	***deleted***

Justification

Moved to Article 5 (4).

Amendment 82
Article 10, Paragraph 2 a (new)

	(2a) Clear guidelines has to be drafted for the functioning of consortia. These guidelines has to take in consideration the following:
	(a) the WTO rules
	(b) a right division of the cost of the tests, of the drafting of the reports and of the working cost of the consortia.
	(c) the guarantee of the confidentiality of certain specific uses
	(d) the possibility for downstream users to notify their use in an early stage
	(e) a code of conduct for third parties

Justification

For big companies and SME is it important to be represented by a third party, as this will certainly encourage SME participation in consortia, as they lack often the specific knowledge required. Furthermore is it important that clear rules about the functioning of consortia will be adopted:

- in conformity with WTO rules.

- consortia forming in a confidential way.

- clear arrangements for SMEs in advance about the division of the costs.

- downstream users' applications can be considered in the chemical security analysis.

- confidence in the third party defending their interest.

Amendment 83
Article 11, Paragraph 1

(1) ***The technical dossier referred to in Article 9 (a) shall include under points (vi), (vii) and (viii) of that provision as a minimum the following:***	(1) ***The hazard dossier referred to in Article 9 (a) shall include under points (i), (ii) and (iii) the following information:***
a) ***the information specified in Annex V for substances manufactured or imported in quantities of 1 tonne or more per year per manufacturer or importer;***	a) ***for substances in quantities of 1 tonne or more per year per registrant as a minimum the information on physico-chemical properties specified in Annex V as well as any other for risk characterisation relevant information on physico-chemical, human health and environmental properties of the substance available to the registrant;***
b) ***the information specified in Annexes V and VI for substances manufactured or imported in quantities of 10 tonnes or more per year per manufacturer or importer;***	b) ***for substances in quantities of 10 tonnes or more per year per registrant as a minimum the information specified in Annex V as well as any other for risk characterisation relevant information on physico-chemical, human health and environmental properties of the substance available to the registrant as specified in Annex VI in accordance with the Rules set out in Article 11 a new, Paragraph 2 and 3;***
c) ***the information specified in Annexes V and VI and testing proposals for the provision of the information specified in Annex VII for substances manufactured or imported in quantities of 100 tonnes or more per year per manufacturer or importer;***	c) ***for substances in quantities of 100 tonnes or more per year per registrant the information specified in Annexes V and VI as well as any other for risk characterisation relevant information on physico-chemical, human health and environmental properties of the substance available to the registrant and testing proposals for the not yet available information specified Annex VII in accordance with the Rules set out in Article 11 a new, Paragraph 2 and 3;***

d) ***the information specified in Annexes V and VI and testing proposals for the provision of the information specified in Annexes VII and VIII for substances manufactured or imported in quantities of 1 000 tonnes or more per year per manufacturer or importer.***	d) ***for substances in quantities of 1000 tonnes or more per year per registrant the information specified in Annexes V and VI as well as any other for risk characterisation relevant information on physico-chemical, human health and environmental properties of the substance available to the registrant and testing proposals for the not yet available information specified Annexes VII and VIII in accordance with the Rules set out in Article 11 a new, Paragraph 2 and 3;***

Justification

This amendment specifies that all information available to the registrant have to be submitted in the hazard dossier for a substance for the purpose of registration.

For substances in quantities of 10 to 100 tonnes, in addition to the already available information, all information on the physico-chemical properties and all toxicological and eco-toxicological information specified in Annex V(+) has to be generated. Further information as specified in Annex VI will need to be generated for substances identified in a screening process by the Agency, in order to create additional costs only for substance that might most likely be of risk.

The submission of full information sets for substances between 1 and 100 tonnes is encouraged by the liberation from the obligation to pay a fee.

This amendment extends the system requiring the information in Annex V+ as a starting point and the information in Annex VI for some substances that may pose a high risk after a screening by the Agency to substances in quantities of up to 100 tonnes. For substances in quantities of 100 to 1000 tonnes, the required information is then specified in Annexes V to VII, and for substances in quantities of 1000 tonnes or more, the information requirements are set out in Annexes V to VIII.

Amendment 84
Article 11, Paragraph 2

(2) As soon as the quantity of a substance that has already been registered reaches the next tonnage threshold the appropriate additional information required under paragraph 1***, as well as any updates of the other elements of the registration in the light of this additional information, shall be submitted to the Agency.***	(2) As soon as the quantity of a substance that has already been registered reaches the next tonnage threshold the ***manufacturer or importer shall inform the Agency immediately, and submit to it in the format specified by the Agency a proposal for the*** appropriate additional information required under paragraph 1. ***The registrant shall submit to the Agency this additional information within a timeframe set by the***

Agency which takes into account the time necessary to generate this information.

Justification

This amendment specifies specifies that all information available to the registrant have to be submitted in the hazard dossier for a substance for the purpose of registration.

For substances in quantities of 10 to 100 tonnes, in addition to the already available information, all information on the physico-chemical properties and all toxicological and eco-toxicological information specified in Annex V(+) has to be generated. Further information as specified in Annex VI will need to be generated for substances identified in a screening process by the Agency, in order to create additional costs only for substance that might most likely be of risk.

The submission of full information sets for substances between 1 and 100 tonnes is encouraged by the liberation from the obligation to pay a fee.

This amendment extends the system requiring the information in Annex V+ as a starting point and the information in Annex VI for some substances that may pose a high risk after a screening by the Agency to substances in quantities of up to 100 tonnes. For substances in quantities of 100 to 1000 tonnes, the required information is then specified in Annexes V to VII, and for substances in quantities of 1000 tonnes or more, the information requirements are set out in Annexes V to VIII.

Amendment 85
Article 11, Paragraph 2 a (new)

(2a) The quantity of a substance per year for a phase in substance shall be determined by the average quantity manufactured or imported in the preceding 3 years before the submission of the registration dossier.

Justification

Information requirements increase whenever a tonnage threshold is exceeded. The consequences of this are proportionally more significant whenever the 1 tonne and 10 tonne thresholds are exceeded. It is therefore necessary to permit a degree of flexibility for SMEs, particularly while sourcing. A 3 year average would ensure that more extensive registration requirements would only apply whenever a registrant has consistently exceeded a given tonnage threshold.

Amendment 86

Article 11 a (new)

Risk based waiving of tests

(1) Notwithstanding Article 11, registrants need not perform tests in accordance with Annexes VI, VII and VIII if the risks caused by the substance are adequately controlled on the basis of available information on intrinsic properties and of limited exposure due to risk management measures.

(2) The Commission shall specify in Annex IX conditions for risk based waiving of tests in accordance with the procedure set out in Article 130 (3). These conditions shall take into account the various types of environmental compartments and human populations exposed, the various routes of exposure, the duration and frequency of exposure on the basis of Annex IV Section 5 and the protection of animal lives. In order to ensure proportionality between the costs and benefits of such tests, these conditions shall be based on a reasonable level of assurance for the demonstration of adequate control.

(3) To make use of exposure based waiving, a registrant shall demonstrate in his hazard dossier either that he fulfils any conditions specified in Annex IX or that the risks caused by the substance adequately controlled by reference to the relevant parts of the chemical safety report.

Justification

Testing should be targeted to the exposure situations envisaged by the registrant. Therefore, in addition to specific rules for waiving of certain tests set out in the testing Annexes (Annexes VI to VIII), as a general rule testing may be omitted if adequate control of the risks can be demonstrated on the basis of already available information on the hazards and the exposure situation or exposure control measures in place.

To facilitate the application of this provision, the Commission should develop general guidance, taking into account the exposure categories as specified in paragraph 2. Registrants will moreover be able to demonstrate adequate control of the risks for their specific case.

Amendment 87
Article 12, Paragraph 2, Subparagraph 1 a (new)

These methods shall be regularly reviewed and improved with a view to reducing experimentation on vertebrates 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 with a view to replacing the animal test method with the alternative one.

Justification

Replaces amendment 22 of the draft report. The test methods should be automatically updated when an alternative test method is validated by ECVAM.

Amendment 88
Article 12, paragraph 3

3. Laboratory tests ***and analyses*** shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and with the provisions of Directive 86/609/EEC.	3. ***New*** laboratory tests ***involving vertebrate animals*** shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 87/18/EEC and with the provisions of Directive 86/609/EEC.

Justification

The repetition of all tests which have already been carried out and which do not comply with GLP would result in a substantial number of renewed, unnecessary tests on vertebrate animals. Even tests already carried out which do not comply with GLP provide reliable results for the purposes of registration and evaluation.

Consequently, for reasons of cost-effectiveness GLP, an expensive obligation, should be confined to new tests on vertebrate animals.

Other information, for example physico-chemical data, could be produced more cheaply without falling below the requisite standard.

Amendment 89
Article 12, Paragraph 4

(4) If a substance has already been registered, a new registrant shall be entitled to refer to studies and test reports, hereinafter "studies", for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered***, including*** the degree of purity and the nature of impurities, and that he can submit a letter of access from the previous registrant(s) allowing the use of the studies.	(4) If a substance has already been registered, a new registrant shall be entitled to refer to studies and test reports, hereinafter "studies", for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered. ***The substance is considered to be the same, if*** the degree of purity and the nature of impurities ***are similar and do not modify its toxicity profile***. ***The new registrant shall*** submit a letter of access from the previous registrant(s) allowing the use of the studies.

Justification

This amendment will considerably improve the workability of the regulation. As the first registrant has to provide information on the purity of the substance (Annex IV.2.), it ensures that a substance does not have to be registered several times simply because its purity and the nature of impurities might vary without having a negative effect on the toxicity profile.

Amendment 90
Article 12, paragraph 4

4. If a substance has already been registered, a new registrant shall be entitled to refer to studies and test reports, hereinafter "studies", for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that he ***can submit*** a letter of access from the previous registrant(s) ***allowing the use of the studies***.	4. If a substance has already been registered, a new registrant shall be entitled to refer to studies and test reports, hereinafter "studies", for the same substance submitted earlier, provided that he can show that the substance that he is now registering is the same as the one previously registered, including the degree of purity and the nature of impurities, and that he ***submits*** a letter of access from the previous registrant(s).

Justification

Access must be guaranteed to data on tests not carried out on animals, as is already provided for in connection with tests carried out on animals. This amendment is linked to the other amendments tabled to the articles in Title II: Registration of substances.

Amendment 91
Article 13, Paragraph 2, Introductory part

(2) A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a preparation if the concentration of the substance in the preparation is less than the lowest of any of the following:	(2) A chemical safety assessment in accordance with paragraph 1 need not be performed for a substance which is present in a preparation ***or article*** if the concentration of the substance in the preparation ***or article*** is less than the lowest of any of the following:

Amendment 92
Article 13, paragraph 3, point (d)

(d) PBT and vPvB assessment.	***Deleted***

Justification

There is no need for a separate evaluation of PBT and vPvB substances. An evaluation of these properties is already required as part of the hazard assessment under paragraph 3(a) and (c).

Amendment 93
Article 13, Paragraph 4, Subparagraph 2

The exposure assessment and the risk characterisation shall address all identified uses of the manufacturer or importer.	The exposure assessment and the risk characterisation shall address all identified uses ***or use and exposure categories*** of the manufacturer or importer ***and shall result in a set of risk management measures and operational conditions that ensure adequate control of the risks.***

Justification

Substance manufacturers are not able to carry out detailed individual evaluations for all conceivable conditions of use. This would also not be desirable for the following reasons: A too detailed description of the safe conditions of use restricts the necessary flexibility of substance use and relies on the extensive transfer of (possibly sensitive) application related know-how to the substance manufacturer. The concept of use and exposure categories is independent from individual uses. Therefore it makes the communication in the supply chain workable.

Amendment 94
Article 13, paragraph 5, point (b)

(b) in cosmetic products within the scope of Council Directive 76/768/EEC[1].	***Deleted***

[1] OJ L 262 , 27.9.1976, p. 169.

Justification

This Directive is included in the list of exemptions specified in Article 2(1a) (new).

Amendment 95
Article 17, Paragraph 1

(1) When an on-site isolated intermediate or transported isolated intermediate 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 the other manufacturers and/or importers in accordance with the second and third subparagraphs.	(1) When an on-site isolated intermediate or transported isolated intermediate 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***, under fully respect of the competition rules,*** for the purposes of registration. Parts of the registration shall be submitted by one manufacturer or importer acting, with their agreement, on behalf of the other manufacturers and/or importers in accordance with the second and third subparagraphs.

Justification

The formation of a consortium between two manufactories or importers of the same substance with the purpose of a registration, is an important step forward to a more effective and cost realistic chemical substance policy. The formation of such consortiums has to be however in full respect of the competition rules, and in particular with art. 81 of the Treaty concerning agreements and decisions made between enterprises and their potential effect on the competition on the market.

Amendment 96
Article 17, Paragraph 2

2. Each registrant who is a member of a consortium shall pay ***only one-third*** of the	2. Each registrant who is a member of a consortium shall pay ***an appropriate share***

fee.	of the fee.

Justification

Costs should be shared under a flexible system so as to encourage registrants to form consortia (cf. justification concerning Article 10(2)).

Amendment 97
CHAPTER 6, title

TRANSITIONAL PROVISIONS APPLICABLE TO PHASE-IN SUBSTANCES AND NOTIFIED SUBSTANCES	***Deleted***

Amendment 98
TITLE II a (new)

TRANSITIONAL PROVISIONS APPLICABLE TO THE REGISTRATION OF SUBSTANCES

Justification

The new Title IIa means that uniform pre-registration for all substances will be achieved by a certain point. This will ensure greater planning certainty for manufacturers, processors, users and authorities. Owing to early cooperation and the easier formation of consortia (e.g. OSOR), fewer substances will disappear from the market. This will ease the burden on SMEs, in particular, and downstream users. The most important information about the properties of substances and exposure to them will be available after only five years.

Amendment 99
CHAPTER I (new)

PRINCIPLES

Amendment 100
Article 20 a (new), title

Article 20a

Scope of transitional provisions

Amendment 101
Article 21, Paragraph 2 a (new)

(2a) Article 19 shall not apply for a period of 9 years after entry into force of this Regulation to phase-in substances manufactured in the Community or imported, in quantities reaching 10 tonnes or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation.

Justification

The text of the commission proposal remains with exception of the amendment above.

This amendment introduces an additional registration deadline for substances between 10 and 100 tonnes 9 years after the entry into force. This spreads the workload for phase in substances more evenly in the transitional period both for enterprises and the Agency.

Amendment 102
Article 22, paragraph 1

1. A notification submitted in accordance with Directive 67/548/EEC shall be regarded as a registration for the purposes of ***this Title*** and the Agency shall assign a registration number within one year of entry into force of this Regulation.	1. A notification submitted in accordance with Directive 67/548/EEC shall be regarded as a registration ***and evaluation*** for the purposes of ***Titles II and VI*** and the Agency shall assign a registration number within one year of *the* entry into force of this Regulation. ***An evaluation carried out pursuant to Regulation (EEC) No 793/93 or in accordance with another comparable, internationally recognised procedure before this Regulation enters into force shall be regarded as a registration and evaluation for the purposes of this Title; the Agency shall assign a registration number within one year of the entry into force of this Regulation.***

Justification

Such substances have already been evaluated under the new substances notification procedure or the Regulation concerning old substances. Those evaluations must be recognised. Re-submitting the documents would be unnecessary bureaucracy.

Amendment 103
Chapter - I (new)

PRE-REGISTRATION

Justification

These amendments introduce a single pre-registration deadline for all phase-in substances. The pre-registered substances will be included in a register of substances and will be published. This will ensure transparency about which phase- in substances are on the market and it will indicate the earliest registration deadline for each substance.

These amendments will encourage the formation of consortia, and thereby save the lives of animals and reduce costs for enterprises. They also facilitate the organisation within the Agency during the phase- in period.

Amendment 104
Article 22 a (new)

Obligation to notify <u>phase-in</u> substances to the register of substances

(1) Save as otherwise provided in this Regulation, not more than 18 months after the entry into force of this Regulation any manufacturer or importer who manufactures or imports a phase-in substance, either on its own or in a preparation, in quantities of 1 tonne or more per year must notify to the Agency, for inclusion in the register of substances, the information referred to in paragraph 2.

(2) The following information is to be notified in the format specified by the Agency in accordance with Article 108:

a) the name and address of the manufacturer or importer and the name of the contact person; and the name of any representative in accordance with Article 22 b paragraph 3;

b) a statement indicating whether consent is given for the publication, pursuant to Article 22b(2), of the name and address of the manufacturer or importer or of the appointed representative;

c) the name of the substance and, where applicable, the group of substances,

including its EINECS and CAS number, if available;

d) production volumes per year in tonnage bands (> 1 tonne, > 10 tonnes, > 100 tonnes, > 1000 tonnes);

e) an indication of the toxicological or ecotoxicological endpoints for which the manufacturer or importer has relevant studies from his own tests on vertebrate animals;

f) a statement as to whether the substance is used exclusively as an on-site or transported isolated intermediate;

g) initial information on use and exposure categories as specified in Annex IV section 5;

h) a statement as to whether the manufacturer or importer is prepared to collaborate in a consortium in accordance with Article 10.

(3) If the period referred to in paragraph 1 has elapsed the Agency may, in justified cases, permit a late notification to the register of substances, in accordance with paragraph 2, of an application made within a late notification period of a further six months after the publication of the register in accordance with Article 22 b (2). If the Agency rejects a late notification, an appeal may be brought against that decision in accordance with the provisions of Articles 87, 88 and 89.

(4) Manufacturers and importers who do not submit the information required under paragraph 2 shall not be able to rely on Article 21.

(5) The Agency shall assign a number (pre-registration number) to the notification to the register of substances in accordance with Article 22a, and also record the date on which the notification was received by the Agency, and shall inform the manufacturer or importer of the pre-registration number and the date of receipt without delay.

Justification

These amendments introduce a single pre-registration deadline for all phase-in substances. The pre-registered substances will be included in a register of substances and will be published. This will ensure transparency about which phase- in substances are on the market and it will indicate the earliest registration deadline for each substance.

These amendments will encourage the formation of consortia, and thereby save the lives of animals and reduce costs for enterprises. They also facilitate the organisation within the Agency during the phase- in period.

Amendment 105
Article 22 b (new)

Register of substances

(1) The Agency shall operate a register of substances containing the information specified in Article 22a.

(2) The Agency shall publish all notified substances in the register of substances without delay after the expiry of the notification period laid down in Article 22a(1), indicating:

a) the name of the substance and, where applicable, the group of substances, including its EINECs and CAS number, if available;

b) where applicable, the name and address of the manufacturer or importer, provided that consent pursuant to Article 22a(2)(b)has been given;

c) the toxicological or ecotoxicological endpoint for which studies from tests on vertebrate animals are available;

d) the earliest deadline for the registration of each substance in accordance with Article 21.

(3) Any manufacturer and importer may appoint a natural or legal person established in the Community as his representative to be published on the webpage. Provided the name of such a representative has been notified to the Agency according to Art. 22a (1) (a), the identity of the manufacturer or importer

shall not be made available by the Agency according to paragraph 2.

(4) The Agency shall publish the information pursuant to paragraph 2 for the late notifications permitted pursuant to Article 22a(3) within one month of the expiry of the late notification period.

(5) Downstream users must inform the Agency, within one year of the publication of the register of substances pursuant to Article 22b(2), of the existence of studies from their own tests on vertebrate animals for toxicological or ecotoxicological endpoints. The Agency shall supplement the register of substances and publish that supplement 13 months after the publication of the register.

Justification

These amendments introduce a single pre-registration deadline for all phase-in substances. The pre-registered substances will be included in a register of substances and will be published. This will ensure transparency about which phase- in substances are on the market and it will indicate the earliest registration deadline for each substance.

This early publication of all phase-in substances enables communication both between manufacturers and importers to prepare the registration dossiers and between suppliers and downstream users. Downstream users will know which substances are supported by their suppliers. In case a substance has not been pre-registered by their suppliers within 18 months, downstream users will be given the opportunity to either find a new supplier or to manufacture or import the substance themselves, and are given an additional 6 months to pre-register those substances.

Amendment 106
Article 23, Paragraph 1

(1) In order to avoid unnecessary animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort. ***It is also necessary to take measures limiting unnecessary duplication of other tests.***	(1) In order to avoid unnecessary animal testing, testing on vertebrate animals for the purposes of this Regulation shall be undertaken only as a last resort.

Justification

These amendments (and consequential listed below) ensure that mandatory sharing of data is extended to information derived from non-vertebrate animal tests. The aim of OSOR is to increase health and environmental protection, whilst ensuring best use of industries' resources, by sharing, at a cost, all hazard data.

Part of OSOR package.

Amendment 107
Article 23, paragraph 3

(3) Any summaries or robust study summaries of studies submitted in the framework of a registration at least ***10*** years previously may be made freely available by the Agency to any other registrants or potential registrants.	(3) Any summaries or robust study summaries of studies submitted in the framework of a registration at least ***15*** years previously may be made freely available by the Agency to any other registrants or potential registrants.

Justification

Surrendering the data is a considerable encroachment on property rights. The period should therefore be extended to at least 15 years.

Amendment 108
Article 23, Paragraph 4

(4) ***With regard to tests not involving vertebrate animals, this Title shall apply to potential registrants only if previous registrants have made an affirmative declaration for the purposes of point (x) of Article 9(a).***	(4) ***Any potential registrant may appoint a third party representative to participate in the SIEF. The name of the representative shall be used in the database established under this Title. The representative shall have sufficient experience in the interpretation of hazard information.***

Justification

Sets out the principle of one dataset per substance. Deletes paragraph 4 because it is now redundant (linked to amendment 77).

Amendment 109
Article 23, Paragraph 4 a (new)

	(4a) Any downstream user may appoint a third party representative to participate in the SIEF.

Justification

Sets out the principle of one dataset per substance. Deletes paragraph 4 because it is now redundant (linked to amendment 77).

Amendment 110
Article 24, Paragraph 1

(1) Before testing on vertebrate animals is carried out in order to meet information requirements for the purposes of registration, paragraphs 2, 3 and 4 shall apply.	(1) Before testing on vertebrate animals is carried out in order to meet information requirements for the purposes of registration, ***any potential registrant shall inquire from the Agency whether a registration has already been submitted for the same substance. He shall submit all the following information to the Agency with the enquiry:***
	a) his identity;
	b) the identity of the substance, as referred to in sections 2.1 and 2.3 of Annex IV;
	c) which information requirements would require new studies involving vertebrate animals to be carried out by him.

Justification

Maintains the obligation to share all animal data and extends it to give a right to registrants to require other information to be shared.

Amendment 111
Article 24, Paragraph 2

(2) The potential registrant shall consult the	(2) ***Any*** potential registrant ***may submit a***

database referred to in Article 73(2)(d) in order to find out whether the same substance has already been registered.	***list of information requirements that would require new studies to be carried out by him, specifying the information set out in paragraph 1(a) and (b).***

Justification

Maintains the obligation to share all animal data and extends it to give a right to registrants to require other information to be shared.

Amendment 112
Article 24, Paragraph 3

(3) The potential registrant shall inquire from the Agency whether a registration has already been submitted for the same substance. He shall submit all the following information to the Agency with the inquiry:	***deleted***
a) his identity;	
b) the identity of the substance, as referred to in sections 2.1 and 2.3 of Annex IV;	
c) which information requirements would require new studies involving vertebrate animals to be carried out by him;	
d) which information requirements would require other new studies to be carried out by him.	

Justification

Maintains the obligation to share all animal data and extends it to give a right to registrants to require other information to be shared.

Amendment 113
Article 24, paragraph 5, subparagraph 1

5. If the same substance has previously been registered less than ***10*** years earlier, the Agency shall inform the potential registrant without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries of the	5. If the same substance has previously been registered less than ***15*** years earlier, the Agency ***shall ascertain whether the previous registrant consents to the disclosure of his name. In this case the Agency*** shall inform the potential registrant

studies, as the case may be, already submitted by them involving vertebrate animals.	without delay of the names and addresses of the previous registrant(s) and of the relevant summaries or robust study summaries of the studies, as the case may be, already submitted by them involving vertebrate animals.

Justification

The identity of the previous registrant is confidential information pursuant to Article 116.

Amendment 114
Article 25, paragraph 1

1. In the case of substances previously registered less than ***10*** years earlier as referred to in Article 24(5), the potential registrant shall ask the previous registrant(s) for the information involving tests on vertebrate animals he requires in order to register. He may ask the registrants for any information on tests not involving vertebrate animals for which the previous registrants have made an affirmative declaration for the purposes of point (x) of Article 9(a).	1. In the case of substances previously registered less than ***15*** years earlier as referred to in Article 24(5), the potential registrant shall ask the previous registrant(s) for the information involving tests on vertebrate animals he requires in order to register. He may ask the registrants for any information on tests not involving vertebrate animals for which the previous registrants have made an affirmative declaration for the purposes of point (x) of Article 9(a).

Amendment 115
Article 25, paragraph 5

5. The previous registrant(s) shall have 1 month from the receipt of the information referred to in paragraph 4 to inform the potential registrant and the Agency of the cost incurred by him for the study concerned. At the request of the potential registrant, the Agency shall take the decision to make available to him the summaries or robust study summaries, as the case may be, of the studies concerned, or the results thereof, on receipt of proof that he has paid the previous registrant(s) ***50% of the cost shown by the latter***.	5. The previous registrant(s) shall have 1 month from the receipt of the information referred to in paragraph 4 to inform the potential registrant and the Agency of the cost incurred by him for the study concerned. At the request of the potential registrant, the Agency shall take the decision to make available to him the summaries or robust study summaries, as the case may be, of the studies concerned, or the results thereof, on receipt of proof that he has paid the previous registrant(s) ***a fair share established by the Agency***.

Justification

Costs should be shared fairly and proportionately on the basis of decisions taken by the Agency. This amendment is linked to the other amendments to the articles contained in Title III: Data sharing and avoidance of unnecessary testing.

Amendment 116
Article 25, paragraph 6

6. If the previous registrant(s) fail(s) to inform the potential registrant and the Agency of the cost within the deadline set in paragraph 5, the Agency, on request, shall take the decision to make available to the potential registrant the summaries or robust study summaries, as the case may be, of the studies concerned as required by him. The previous registrant(s) shall have a claim on the potential registrant for ***50% of the cost***, which shall be enforceable in the national courts.	6. If the previous registrant(s) fail(s) to inform the potential registrant and the Agency of the cost within the deadline set in paragraph 5, the Agency, on request, shall take the decision to make available to the potential registrant the summaries or robust study summaries, as the case may be, of the studies concerned as required by him. The previous registrant(s) shall have a claim on the potential registrant for ***a fair share established by the Agency***, which shall be enforceable in the national courts.

Justification

Costs should be shared fairly and proportionately on the basis of decisions taken by the Agency. This amendment is linked to the other amendments to the articles contained in Title III: Data sharing and avoidance of unnecessary testing.

Amendment 117
Article 25, paragraph 6

6. If the previous registrant(s) fail(s) to inform the potential registrant and the Agency of the cost within the deadline set in paragraph 5, the Agency, on request, shall take the decision to make available to the potential registrant the summaries or robust study summaries, as the case may be, of the studies concerned as required by him. The previous registrant(s) shall have a claim on the potential registrant for ***50%*** of the cost, which shall be enforceable in the national courts.	6. If the previous registrant(s) fail(s) to inform the potential registrant and the Agency of the cost within the deadline set in paragraph 5, the Agency, on request, shall take the decision to make available to the potential registrant the summaries or robust study summaries, as the case may be, of the studies concerned as required by him. The previous registrant(s) shall have a claim on the potential registrant for ***a fair share*** of the cost, which shall be enforceable in the national courts.

Amendment 118
Article 26

Duty to pre-register for phase-in substances ***deleted***

(1) In order to benefit from the transitional regime provided for in Article 21 each potential registrant of a phase-in substance shall submit all the following information to the Agency in the format specified by the Agency in accordance with Article 108:

a) the name of the substance and, where applicable, the group of substances, including its Einecs and CAS number, if available;

b) his name and address and the name of the contact person;

c) the envisaged deadline for the registration/tonnage band;

d) an indication of the physicochemical, toxicological and ecotoxicological endpoints/properties for which he has relevant studies or information available to him for the purposes of registration information requirements, if any;

e) a statement as to whether or not studies referred to under point (d) include tests on vertebrate animals and, if not, whether he considers making an affirmative declaration for the purposes of point (x) of Article 9(a) with his registration.

The potential registrant may limit the information to be submitted under the first subparagraph to those endpoints/properties for which tests were required.

(2) The information referred to in paragraph 1 shall be submitted at the latest 18 months before:

a) the deadline laid down in Article 21 (1) for phase-in substances manufactured or imported in quantities of 1 000 tonnes or more per year;

b) the deadline laid down in Article 21 (2) for phase-in substances manufactured or imported in quantities of 1 tonne or more

per year.

(3) Registrants who do not submit the information required under paragraph 1 shall not be able to rely on Article 21.

(4) Manufacturers and importers of phase-in substances in quantities of less than 1 tonne per year, as well as downstream users, may submit the information referred to in paragraph 1 to the Agency in the format specified by the Agency in accordance with Article 108.

(5) The Agency shall record the information submitted in accordance with paragraphs 1 to 4 in a database. It shall grant access to these data held on each substance to the manufacturers and importers who have submitted information on that substance in accordance with paragraphs 1 to 4. The competent authorities of the Member States shall also have access to this data.

Justification

This Article is not necessary anymore as a consequence of the new Articles 22a to d

Amendment 119
Article 27, Paragraph 1

(1) All manufacturers ***and*** importers who have submitted information to the Agency in accordance with Article 26 ***for*** the same phase-in substance shall be participants in a substance information exchange forum (SIEF).	(1) All manufacturers**,** importers ***and downstream users*** who have submitted information to the Agency in accordance with Article 26***a and all registrants of*** the same phase-in substance shall be participants in a substance information exchange forum (SIEF), ***until the expiry of the deadline in Article 21(3).***

Justification

Together with the amendments to articles 5(4) and 43a and the existing text of article 111(2)(b), this amendment strongly encourages registrants to agree on the interpretation of hazard data with the aim of achieving one dataset per substance. this amendments also clarifies the duration of SIEF to ensure that the data is available to SMEs registering in low volumes.

Amendment 120
Article 27, Paragraph 2 a (new)

(2a) SIEF participants shall make every effort to agree on the interpretation of the information that they exchange. This concerns in particular the elements in Article 110(1) (c), (d) and (e).

Justification

Together with the amendments to articles 5(4) and 43a and the existing text of article 111(2)(b), this amendment strongly encourages registrants to agree on the interpretation of hazard data with the aim of achieving one dataset per substance. this amendments also clarifies the duration of SIEF to ensure that the data is available to SMEs registering in low volumes.

Amendment 121
Article 27, Paragraph 2 b (new)

(2b) If information required in respect of the application of Annexes V to VI is not available in the SIEF, only one study shall be conducted within each SIEF by one member of the SIEF acting on behalf of the other members.

Justification

Article 27(2a) allows the use of a third party to represent potential registrants in a SIEF. This allows potential registrants to conceal their identity from other potential registrants. They will, however, still need to identify themselves to the Agency.

Part of OSOR package.

Amendment 122
Article 27, Paragraph 2 c (new)

(2c) If information required in respect of the application of Annexes VII to VIII is

	not available in the SIEF, any proposals for further testing submitted for the purposes of Annexes VII or VIII shall indicate which company shall carry out each test in the event that the test is required.

Justification

Article 27(2a) allows the use of a third party to represent potential registrants in a SIEF. This allows potential registrants to conceal their identity from other potential registrants. They will, however, still need to identify themselves to the Agency.

Part of OSOR package.

Amendment 123
Article 28, paragraph 1

1. Before testing on vertebrate animals 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 consulting the ***database*** referred to in ***Article 26*** and by communicating within his SIEF. If a relevant study is available within the SIEF, a participant of that SIEF who would have to carry out a test on vertebrate animals shall request that study ***within two months of the deadline set in Article 26(2)***.	1. Before testing on vertebrate animals 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 consulting the ***substance register*** referred to in ***Article 22b*** and by communicating within his SIEF. If a relevant study is available within the SIEF, a participant of that SIEF who would have to carry out a test on vertebrate animals shall request that study.

Justification

Follows from previous amendments, since Article 26 is to be deleted. The information will instead be contained in the substance register referred to in Article 22b.

Requests for existing studies involving animal experiments should not be subject to a time limit, since studies will be required either in order to compile core information within the meaning of Article 22c or else at the time of registration. Furthermore, it must be permissible to request studies at an earlier stage if, for example, the intention is to register earlier.

Amendment 124
Article 28, Paragraph 1 a (new)

	(1a) Before studies not involving vertebrate

animals are carried out in order to meet the information requirements for the purposes of registration, a SIEF participant may inquire whether a relevant study is available by consulting the database referred to in Article 26 and by communicating within his SIEF. If a relevant study is available within the SIEF, a participant of that SIEF who would have to carry out a study may request that study.

Justification

This amendment creates the obligation to share non-animal data if it is requested. It also clarifies which SIEF participants should carry out the testing. Furthermore, it clarifies that SMEs registering in low volumes do not have to request and pay for data until their registration is imminent.

Amendment 125
Article 28, Paragraph 1 b (new)

(1b) Within two weeks of a request made under paragraphs 1 or 1a, the owner of the study shall provide proof of its cost to the participant(s) requesting it. The participant(s) and the owner shall take all reasonable steps to reach an agreement on how to share the cost. If they cannot reach such an agreement, the cost shall be shared equally. The owner shall provide the study within two weeks of receipt of payment.

Justification

This amendment creates the obligation to share non-animal data if it is requested. It also clarifies which SIEF participants should carry out the testing. Furthermore, it clarifies that SMEs registering in low volumes do not have to request and pay for data until their registration is imminent.

Amendment 126
Article 28, paragraph 2

2. If a relevant study involving tests on	2. If a relevant study involving tests on

vertebrate animals is not available within the SIEF, the participant shall contact other participants of that SIEF who have submitted information about ***the same or a similar use of the substance*** and who might need to carry out that study. ***They*** shall take all reasonable steps to reach an agreement as to who is to carry it out on behalf of the other participants.	vertebrate animals is not available within the SIEF ***for a particular use and exposure category***, the participant shall contact other participants of that SIEF who have submitted information about ***it*** and who might need to carry out that study. ***The participants*** shall take all reasonable steps to reach an agreement as to who is to carry it out on behalf of the other participants.

Justification

Amendment necessitated by the introduction of use and exposure categories, including linguistic simplification.

Amendment 127
Article 28, Paragraph 2

(2) If a relevant study involving tests on vertebrate animals is not available within the SIEF, the participant shall contact other participants of that SIEF who have submitted information about the same or a similar use of the substance and who might need to carry out that study. They shall take all reasonable steps to reach an agreement as to who is to carry it out on behalf of ***the other*** participants.	(2) If a relevant study involving tests on vertebrate animals is not available within the SIEF, the participant shall contact other participants of that SIEF who have submitted information about the same or a similar use of the substance and who might need to carry out that study. They shall take all reasonable steps to reach an agreement as to who is to carry it out on behalf of ***all*** participants ***who need it to register***.

Justification

This amendment creates the obligation to share non-animal data if it is requested. It also clarifies which SIEF participants should carry out the testing. Furthermore, it clarifies that SMEs registering in low volumes do not have to request and pay for data until their registration is imminent.

Amendment 128
Article 28, paragraph 3

3. If the owner of a study as referred to in paragraph 2 refuses to provide either proof of the cost of that study or the study itself to another participant(s), ***the other***	3. If the owner of a study as referred to in paragraph 2 refuses to provide either proof of the cost of that study or the study itself to another participant(s), ***the Agency shall***

participant(s) shall proceed as if no relevant study were available within the SIEF, unless a registration containing the summary or robust study summary, as the case may be, of the study has already been submitted by another registrant. In such cases, the Agency shall take the decision to make available to the other participant(s) that summary or robust study summary, as the case may be. The other registrant shall have a claim on the participants for an equal share of the cost, which shall be enforceable in the national courts.	***intervene to ensure that the data are shared and that the payment is fair and proportional***.

Justification

The amendment seeks to ensure that data can be shared and, in particular, that excessively high costs are not imposed on SMEs. It is linked to the other amendments to the articles contained in Title III: Data sharing and avoidance of unnecessary testing.

Amendment 129
Article 28 a (new), Title

	Competence and legal protection

Amendment 130
Article 28a (new), paragraph 1

	1. The Agency shall be competent to take decisions under this Title save as otherwise provided.

Justification

For clarity, it should be expressly stated that the Agency is competent for the purposes of Title III as a whole.

Amendment 131
Article 28a (new), paragraph 2

2. An appeal against Agency decisions under this Title may be brought in accordance with Articles 87, 88, and 89.

Justification

Rather than listing cases as and where they arise, the right of appeal should be laid down in one place.

Amendment 132
Article 28 a (new)

(***1) In case of multiple registrants for one substance registered in quantities below 10 tonnes, and in respect of which further information set out in Annex V is required in accordance with Article 43a, the Agency shall inform all those registrants of the identity of each other. The registrants shall have [6] months to agree on who is to generate the information on behalf of all of them.***

(2) In case of failure to reach agreement, the Agency shall designate one of the registrants with the greatest experience in generating information to be responsible for the generation of the information.
(3) The costs for the generation of the further information required shall be shared equally among all registrants of that substance unless another agreement has been reached.

Justification

In the case of substances for which there are multiple registrants, the cost of generating the further information should be shared equally among the registrants. The principle of 'one substance one registration' should be applied in order to further reduce the costs for low volume registrants and for SMEs in particular. The submission of one set of further information would also eliminate the need to agree on the interpretation of test information.

Amendment 133
Article 29, paragraph 1, subparagraph 1 a (new)

	This shall not apply to substances and preparations placed on the market in quantities less than 1 kg per year or supplied once only for scientific research and development purposes.

Justification

To require a safety data sheet to be produced for very small quantities or a one-off supply (for a university teacher, for instance) would be going too far.

Amendment 134
Article 29, paragraph 3

3. Where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0.2 % by volume for gaseous preparations at least one substance posing health or environmental hazards, or one substance for which there are Community workplace exposure limits, the person who is responsible for placing that preparation on the market, whether the manufacturer, importer, downstream user or distributor, shall supply***, at the request of a downstream user,*** a safety data sheet compiled in accordance with Annex Ia.	3. Where a preparation does not meet the criteria for classification as dangerous in accordance with Articles 5, 6 and 7 of Directive 1999/45/EC, but contains in an individual concentration of ≥ 1 % by weight for non-gaseous preparations and ≥ 0.2 % by volume for gaseous preparations at least one substance posing health or environmental hazards, or one substance for which there are Community workplace exposure limits, the person who is responsible for placing that preparation on the market, whether the manufacturer, importer, downstream user or distributor, shall supply a safety data sheet compiled in accordance with Annex Ia.

Justification

When hazardous substances are involved, a safety data sheet should be sent automatically to downstream users.

Amendment 135
Article 29, paragraph 6, second subparagraph

Where a chemical safety assessment is performed the relevant exposure scenarios shall be ***placed*** in ***an annex to*** the safety data sheet.	Where a chemical safety assessment is performed the relevant exposure scenarios ***or exposure categories*** shall be ***described*** in ***the appropriate sections*** of the safety data sheet ***and/or supplied electronically***.

Justification

To incorporate annexes in safety data sheets to cover different exposure scenarios would run counter to the existing international requirements for the sheets. To have a plethora of annexes setting out different exposure scenarios would be unwieldy in practice and entail unacceptable expense, especially for SMEs, because a safety data sheet specifies both the use to which a substance is put and the risk management measures. Furthermore, safety data sheets have to conform to GHS requirements.

Amendment 136
Article 29, paragraph 6, subparagraph 2

Where a chemical safety assessment is performed the relevant exposure scenarios shall be placed in ***an annex to*** the safety data sheet.	Where a chemical safety assessment is performed the relevant exposure scenarios ***or relevant use and exposure categories*** shall be ***indicated under the corresponding headings of*** the safety data sheet ***and/or made available electronically***.

Justification

More precise version of the original Amendment 135 following the introduction of use and exposure categories.

Amendment 137
Article 29, paragraph 7

7. For identified ***uses***, a downstream user shall use appropriate information from the safety data sheet supplied to him.	7. For identified ***uses or use and exposure categories***, a downstream user shall use appropriate information from the safety data sheet supplied to him.

Justification

Needless expenditure would be incurred if safety data sheets had to be sent out again purely because the regulation had entered into force, even when users already had them.

Amendment 138
Article 29, paragraph 8

8. A safety data sheet shall be supplied on paper or electronically at the latest at the time of the first delivery of a substance following the entry into force of this	8. ***Where no safety data sheet conforming to the requirements laid down in Article 29(6) has been supplied before this Regulation entered into force,*** a safety data

Regulation. Suppliers shall update it without delay on the following occasions:	sheet shall be supplied on paper or electronically at the latest at the time of the first delivery of a substance following the entry into force of this Regulation. Suppliers shall update it without delay on the following occasions:

Justification

Needless expenditure would be incurred if safety data sheets had to be sent out again purely because the regulation had entered into force, even when users already had them.

Amendment 139
Article 29, Paragraph 8 a (new)

	(8a) The Commission shall organise the development of technical guidelines setting minimum requirements for safety data sheets, to ensure a clear and adequate information provision for optimal use by all actors up and down the supply chain.

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 140
Article 30, Title

Duty to communicate information down the supply chain for substances and preparations for which a safety data sheet is not ***required***	Duty to communicate information down the supply chain for substances and preparations for which a safety data sheet is not ***supplied***

Justification

Correction to the original Amendment 138.

Amendment 141
Article 30, paragraph 1

1. All actors in the supply chain of a substance on its own or in a preparation who do not ***have to*** supply a safety data sheet in accordance with Article 29 shall communicate the following information down the supply chain to the immediate downstream user or distributor:	1. All actors in the supply chain of a substance on its own or in a preparation who do not supply a safety data sheet in accordance with Article 29 shall communicate the following information down the supply chain to the immediate downstream user or distributor:

Justification

The above provision should not apply when a safety data sheet is supplied, even when there is no requirement to do so under Article 29.

Amendment 142
Article 30, paragraph 1, point (a)

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

Justification

If substances not classed as dangerous are used in preparations, their registration numbers should not have to be specified on safety data sheets when the mandatory particulars for safety data sheets concerning dangerous preparations are confined to the registration numbers of hazardous ingredients and non-hazardous ingredients are excluded.

Amendment 143
Article 30, Paragraph 2, Introductory part

(2) Information shall be communicated in writing at the latest at the time of the first delivery of a substance following the entry into force of this Regulation. Suppliers shall update this information and communicate it down the supply chain without delay on the following occasions:	(2) Information shall be communicated in writing ***or electronically*** at the latest at the time of the first delivery of a substance following the entry into force of this Regulation. Suppliers shall update this information and communicate it down the supply chain without delay on the following occasions:

Justification

Permit new information transfer technology.

Amendment 144
Article 31 a (new), title

Duty to communicate information on substances contained in articles

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.

Amendment 145
Article 31 a (new)

31a. 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. A consumer is not a recipient.

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

Justification

Amendment 146
Article 34, Paragraph 1

(1) A downstream user may provide information to assist in the preparation of a registration.	(1) A downstream user may provide information to assist in the preparation of a registration. ***The information may be submitted directly to the Agency. The provisions of Title III relating to data sharing shall apply to the downstream user, mutatis mutandis.***

Justification

Without having the possibility to report directly to the agency, downstream users' right for data protection would be seriously jeopardised. Otherwise the data would be available to the supplier without the chance to control how this information is used.

Amendment 147
Article 34, paragraph 2

2. Any downstream user shall have the right to make a use known in writing to the manufacturer, importer or downstream user who supplies him with a substance with the aim of making ***this*** an identified use. In so doing, he shall provide sufficient information to allow his supplier to ***prepare an exposure scenario for his use*** in the supplier's chemical safety assessment.	2. Any downstream user shall have the right to make a use, ***categories of use, or exposure categories*** known in writing to the manufacturer, importer or downstream user who supplies him with a substance with the aim of making ***these*** an identified use. In so doing, he shall provide sufficient information to allow his supplier ***to take them into account*** in the supplier's chemical safety assessment.

Justification

Instead of specifying individual uses, categories of use and exposure categories should be deemed to suffice, thus ensuring that users will not have to reveal any business or trade secrets to their upstream suppliers.

Amendment 148
Article 34, paragraph 3

3. For registered substances, the manufacturer or importer shall comply with the obligation laid down in Article 13 before he next supplies the substance to the downstream user making the request, provided that the request was made at least one month before the supply, or within 1 month after the request, whichever is the later. For phase-in substances, the manufacturer or importer shall comply with this request and with the obligations laid down in Article 13 before the relevant deadline in Article 21, provided that the downstream user makes his request at least 12 months before the deadline in question.	*Does not affect the English version.*

Justification

More precise formulation of the original Amendment 141 for the benefit of SMEs. It should be required only to indicate use and exposure categories, not special uses. This is particularly important for SMEs (see also the justification to Amendment 4 to Article 3(25)). This does not preclude the right of undertakings to indicate special uses in addition, if they wish to do so for business reasons.

Amendment 149
Article 34, paragraph 4

4. A downstream user of a substance on its own or in a preparation shall prepare a chemical safety report in accordance with Annex XI for any use outside the conditions described in an exposure scenario communicated to him in a safety data sheet.	4. A downstream user of a substance on its own or in a preparation shall prepare a chemical safety report in accordance with Annex XI for any use***, category of use, or exposure category*** outside the conditions described in an exposure scenario***, or in the specified categories of use and exposure categories,*** communicated to him in a safety data sheet. ***This shall apply only to substances used in quantities not less than 1 tonne per year.***

Justification

Downstream users, especially SMEs, should not have to produce a chemical safety report whenever they have put a substance to an individual use not in accordance with the supplier's indications. Instead, that requirement should apply only when they depart from categories of use or exposure categories. The quantity threshold is necessary because downstream users, unlike suppliers or importers, would otherwise have to draw up chemical safety reports even when the quantities involved were minute.

Amendment 150
Article 35, paragraph 1

1. Before commencing ***a particular*** use of a substance that has been registered by an actor up the supply chain in accordance with Articles 5 or 16, any downstream user shall report to the Agency the information specified in paragraph 2 of this Article, if ***a safety data sheet is communicated to him that includes an exposure scenario and the downstream user is using the substance outside the conditions described in that***	1. Before commencing ***the*** use of a substance that has been registered by an actor up the supply chain in accordance with Articles 5 or 16, any downstream user shall report to the Agency the information specified in paragraph 2 of this Article, if ***the use lies outside the exposure scenarios or use and exposure categories indicated by that actor on the relevant safety data sheet***.

exposure scenario.

Justification

Amendment necessitated by the introduction of use and exposure categories, including linguistic simplification.

Amendment 151
Article 35, paragraph 2, point (e)

(e) a brief general description of the use(s);	(e) a brief general description of the use(s)**,** ***categories of use, and exposure categories***;

Amendment 152
Article 35, paragraph 2, point (f)

(f) a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.	***Deleted***

Justification

The proposal for additional testing on vertebrate animals can be removed because the experiments in question are already covered by the information to be provided under Article 35(2)(e), concerning exposure categories not yet taken into account by suppliers/importers, in conjunction with the new Annex IXa.

Amendment 153
Article 35, paragraph 2, subparagraph 1 a (new)

	Where such data are not available, the procedure under Article 25 shall apply.

Justification

The amendment is closely related to and follows on from the amendments to Articles 9(a)(x), 24(5), 25(1) and 26(1). Its aim is to remove the optional aspects of the submission of test data on non-vertebrates by removing this provision. Compulsory access to data is of vital importance to SMEs.

Amendment 154
Title VI

EVALUATION ***OF SUBSTANCES***	EVALUATION

Justification

The name of Title VI should reflect the fact that its provisions cover more than the substances' evaluation.

Amendment 155
Article 37, paragraph -1 (new)

	-1. The scope of this Title shall be limited to the substances for which registration is required under Title II.

Justification

The evaluation procedure is based on information obtained via registration (see, for instance, Article 44, which lays down a procedure for requesting further information and thus clearly only relates to registrants, while indicating that the title concerning evaluation applies only to substances for which registration is required). There is no point in evaluating substances that do not have to be registered. Polymers should be completely excluded from REACH and require their own specific regulation.

Amendment 156
Article 37, paragraph 1

Polymers are exempted from evaluation ***under this Title***.	Polymers are exempted from evaluation.

Justification

The evaluation procedure is based on information obtained via registration (see, for instance, Article 44, which lays down a procedure for requesting further information and thus clearly only relates to registrants, while indicating that the Title concerning evaluation applies only to substances for which registration is required). There is no point in evaluating substances that do not have to be registered. Polymers should be completely excluded from REACH and require their own specific regulation.

Amendment 157
Article 38, title

Competent authority	***Responsibility of the Agency for dossier evaluation***

Justification

The European Chemicals Agency's role in the evaluation phase should be strengthened. We propose that the Agency centralise the evaluation of testing proposals and dossiers. In addition to this, the Agency should be able to call on a European network of experts and evaluation institutes based in the Member States.

(SAGE proposal)

Amendment 158
Article 38, paragraph 1

1. ***For the purposes of Articles 39 to 43, the competent authority shall be the competent authority of the Member State within which the manufacture takes place or the importer is established.***	1. ***The Agency shall be responsible for the evaluation of the testing proposals and registration dossiers.***

Justification

The European Chemicals Agency's role in the evaluation phase should be strengthened. We propose that the Agency centralise the evaluation of testing proposals and dossiers. In addition to this, the Agency should be able to call on a European network of experts and evaluation institutes based in the Member States.

(SAGE proposal)

Amendment 159
Article 38, paragraph 2

2. ***If several manufacturers or importers have formed a consortium in accordance with Articles 10 or 17, the competent authority shall be the competent authority of the one manufacturer or importer submitting data to the Agency on behalf of the others in accordance with Articles 10 or 17.***	2. ***The Agency shall rely, for the performance of these evaluations, on the experts and bodies appearing on the lists drawn up pursuant to Article 83.***

Justification

The European Chemicals Agency's role in the evaluation phase should be strengthened. We propose that the Agency centralise the evaluation of testing proposals and dossiers. In addition to this, the Agency should be able to call on a European network of experts and evaluation institutes based in the Member States.

(SAGE proposal)

Amendment 160
Article 39, paragraphs 1 and 2

1. The ***competent authority*** shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes VII and VIII for a substance.	1. The ***Agency*** shall examine any testing proposal set out in a registration or a downstream user report for provision of the information specified in Annexes VII and VIII for a substance.
2. On the basis of the examination under paragraph 1, the ***competent authority*** shall draft one of the following decisions and that decision shall be taken in accordance with the procedure laid down in Articles 48 and 49:	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 in Articles 48 and 49:

Justification

See amendment to Article 38

Amendment 161
Article 40, Paragraph 1, Introductory Part and Paragraph 2

(1) The ***competent authority*** may examine any registration in order to verify either or	(1) The ***Agency*** may examine any registration in order to verify either or both

both of the following:	of the following:
(2) On the basis of an examination made pursuant to paragraph 1, the ***competent authority*** may prepare a draft decision requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and that decision shall be taken in accordance with ***the procedure laid down in*** Articles 48 and 49.	(2) On the basis of an examination made pursuant to paragraph 1, the ***Agency*** may prepare a draft decision ***within twelve months of the publication of the annual evaluation plan referred to in paragraph 4 below*** requiring the registrant(s) to submit any information needed to bring the registration(s) into compliance with the relevant information requirements and that decision shall be taken in accordance with Articles 48 and 49.

Justification

See justification to Article 38.

Amendment 162
Article 40, paragraph 3 a (new)

	3a. The Agency shall draw up an annual plan for the evaluation of the registration dossiers, with particular regard to assessment of their overall quality. This plan shall specify, in particular, the minimum percentage of dossiers to be evaluated during that period. The plan shall be published on the Agency's website.

Justification

It is important to ensure that a minimum number of dossiers are evaluated.

Amendment 163
Article 40, paragraph 3 b (new)

	3b. The Agency shall prepare an annual report on the results of dossier evaluations it has performed. This report shall include, in particular, recommendations to registrants in order to improve the quality of future registrations. The report shall be

	published on the Agency's website.

Justification

It is important to ensure that a minimum number of dossiers are evaluated.

Amendment 164
Article 41, paragraph 1

1. The ***competent authority*** shall examine any information submitted in consequence of a decision taken under Articles 39 or 40, and draft any appropriate decisions in accordance with Article 39 or 40, if necessary.	1. The ***Agency*** shall examine any information submitted in consequence of a decision taken under Articles 39 or 40, and draft any appropriate decisions in accordance with Article 39 or 40, if necessary.

Justification

Consistency with the amendments to Articles 38 and 40.

Amendment 165
Article 41, paragraph 2

2. Once the dossier evaluation is completed, the ***competent authority*** shall use the information obtained from this evaluation for the purposes of Articles 43a *bis* (1), 56(3) and 66(2), and shall transmit the information obtained to the Commission***, the Agency*** and the ***other*** Member States. The ***competent authority*** shall inform the Commission***, the Agency***, the registrant and the ***competent authorities of the other*** Member States on its conclusions as to whether or how to use the information obtained.	2. Once the dossier evaluation is completed, the ***Agency*** shall use the information obtained from this evaluation for the purposes of Articles 43a *bis* (1), 56(3) and 66(2), and shall transmit the information obtained to the Commission and the Member States. The ***Agency*** shall inform the Commission, the registrant and the Member States on its conclusions as to whether or how to use the information obtained.

Justification

Consistency with the amendments to Articles 38 and 40.

Amendment 166
Article 42, paragraph 1

1. A competent authority that starts evaluating a testing proposal under Article 39 shall notify the Agency accordingly.	***deleted***

Justification

Consistency with the amendment to Article 38.

Amendment 167
Article 42, paragraph 2

2. The ***competent authority*** shall prepare a draft decision in accordance with Article 39(2) within 120 days of receiving a registration or downstream user report containing a testing proposal ***from the Agency***.	2. The ***Agency*** shall prepare a draft decision in accordance with Article 39(2) within 120 days of receiving a registration or downstream user report containing a testing proposal.

Justification

Consistency with the amendment to Article 38

Amendment 168
Article 42, paragraph 3, introductory part

3. In the case of phase-in substances, the ***competent authority*** shall prepare the draft decisions in accordance with Article 39(2):	3. In the case of phase-in substances, the ***Agency*** shall prepare the draft decisions in accordance with Article 39(2):

Justification

Consistency with the amendment to Article 38

Amendment 169
Article 42, paragraph 4

4. ***When the competent authority of a Member State finishes its evaluation activities*** under Article 39 ***in respect of a phase-in substance, it shall notify the Agency accordingly.***	4. ***The list of registration dossiers being evaluated*** under Article 39 ***shall be made available to Member States.***

Justification

Consistency with the amendment to Article 38

Amendment 170
Article 43

1. A competent authority that starts evaluating the compliance of a registration under Article 40 shall notify the Agency accordingly.	***deleted***
2. The ***competent authority*** shall prepare a draft decision in accordance with Article 40(2) within 12 months of the start of the evaluation of the substance.	2. The ***Agency*** shall prepare a draft decision in accordance with Article 40(2) within 12 months of the start of the evaluation of the substance.
3. ***When the competent authority of a Member State finishes its evaluation activities under Article 40 in respect of a phase-in substance, it shall notify the Agency accordingly.***	3. ***The list of registration dossiers being evaluated under Article 40 shall be made available to Member States.***

Justification

Consistency with the SAGE proposal (strengthening the Agency's role in the evaluation phase)

Amendment 171
Chapter 2 a (new)

SCREENING OF REGISTRATION DOSSIERS FOR SUBSTANCES IN QUANTITIES OF 1 TO 100 TONNES

Justification

These amendments enable the Agency to identify substances between 10 and 100 tonnes for which no full Annex VI data set is available as well as substances between 1 and 10 tonnes for which no full Annex V data set, including acute toxicity and biodegradation, is available

and that could pose a high risk. The screening criteria cover dossiers with least hazard information, suspicion of CMR and PBT, widespread exposure, cumulative volumes, and problems identified in enforcement measures. In the interest of workability and proportionality, at least two of these criteria must be met for the substance to be selected.

Furthermore the Agency may suggest further screening criteria to the Commission that is empowered to include such criteria into a new Annex IIIa to this Regulation.

Amendment 172
Article - 43 a (new)

Identification of substances subject to further information requirements

(1) The Agency may perform a screening of all registration dossiers submitted for substances that have only been registered in quantities below 100 tonnes to identify those substances that may pose a high risk because they meet at least two of the criteria set out below:

a) substances with possible high exposure because of:

i) consumer use; or

ii) dispersive professional use; or

iii) dispersive industrial use;

b) substances for which least information has been submitted on human health or environmental properties;

c) substances for which scientific evidence indicates that they are likely to meet the criteria for classification as carcinogenic, mutagenic or toxic for reproduction, category 1 or 2, or to fulfil the criteria in Annex XII, and least information on the indicated hazard property is available;

d) substances which have been registered by at least 20 registrants; unless those registrants have shown that there is no exposure, or scientific evidence has indicated that there is no hazard;

e) substances for which results of enforcement or monitoring activities in the Member States have identified suspicions of risks to human health or the

environment.

(2) The Agency shall require registrants of substances identified as a result of the screening to submit in accordance with Articles 11 a and 12

a) the information set out in Annex VI for substances between 10 and 100 tonnes per year within 2 years; and

b) the information set out in Annex V for substances between 1 and 10 tonnes per year within 1 year.

(3) The Agency may suggest further screening criteria to the Commission. The Commission shall take a decision to include further criteria in Annex IIIA in accordance with the procedure set out in Article 130 (3).

Justification

These amendments enable the Agency to identify substances between 10 and 100 tonnes for which no full Annex VI data set is available as well as substances between 1 and 10 tonnes for which no full Annex V data set, including acute toxicity and biodegradation, is available and that could pose a high risk. The screening criteria cover dossiers with least hazard information, suspicion of CMR and PBT, widespread exposure, cumulative volumes, and problems identified in enforcement measures. In the interest of workability and proportionality, at least two of these criteria must be met for the substance to be selected.

Furthermore the Agency may suggest further screening criteria to the Commission that is empowered to include such criteria into a new Annex IIIa to this Regulation.

Amendment 173
Article - 43 a a (new)

Elaboration of further information in case of multiple registrants

(1) If multiple registrants are required to submit information in accordance with article 43aa (2) for the same substance, the Agency shall inform all those registrants of the identity of each other.

(2) All registrants required to submit the same information shall have three months to agree on who is to generate the

	information on behalf of all of them. In case of failure to reach an agreement, the Agency shall designate one of the registrants who shall generate the information.
	(3) The costs for the generation of the missing information needed to fulfil the requirements of Annexes V or VI respectively shall be shared equally among all registrants of that substance unless another agreement has been reached.

Justification

In case of multiple registrants only one data set will be generated and cost will be shared between all registrants of that substance.

Amendment 173
Article 43a

In order to provide a harmonised approach, the Agency shall develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria for evaluation shall include consideration of hazard data, exposure data and tonnage bands. The Agency shall take a decision on the criteria for the prioritisation of substances for further evaluation. ***Member States shall use these criteria for preparing their rolling plans.***	In order to provide a harmonised approach, the Agency shall develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria for evaluation shall include consideration of hazard data, exposure data and tonnage bands. The Agency shall take a decision on the criteria for the prioritisation of substances for further evaluation.

Justification

Consistency with the SAGE proposal (strengthening the Agency's role in the evaluation phase)

Amendment 174

Article 43a *bis*, title

Competent authority	***Community rolling plan***

Or. fr

Justification

It is essential to have one single Community rolling plan, rather than a superposition of national rolling plans. The Agency should be responsible for developing this draft rolling plan, with due regard for the concerns of Member States.

Amendment 175
Article 43a bis, paragraph 1 (introductory part) and subparagraph 1 a (new)

1. ***A Member State*** shall ***include a substance in*** a rolling plan***, with the aim of becoming competent authority*** for the purposes of Articles 44, 45 and 46, if ***that Member State***, either as a result of a dossier evaluation by its competent authority referred to under Article 38 or from any other relevant source, including information in the registration dossier(s), has reasons for suspecting that the substance presents a risk to health or the environment, ***in particular*** on the basis of either of the following:	1. ***The Agency*** shall ***establish*** a ***draft Community*** rolling plan for the purposes of Articles 44, 45 and 46, ***on the basis of the criteria established under Article 43 a and*** if, either as a result of a dossier evaluation or from any other relevant source, including information in the registration dossier(s), ***it*** has reasons for suspecting that the substance presents a risk to health or the environment, in particular ***for example*** on the basis of either of the following: ***The Agency shall submit its draft rolling plan to Member States by 31 December of each year.***

Justification

It is essential to have one single Community rolling plan, rather than a superposition of national rolling plans. The Agency should be responsible for developing this draft rolling plan, with due regard for the concerns of Member States.

Amendment 176
Article 43a bis, paragraph 1 b (new)

	1b. The Agency shall be responsible for the evaluation of the substances listed on the Community rolling plan. The Agency may, for the performance of substance evaluations, turn to the expert bodies appearing on the list drawn up pursuant to Article 83, which it shall select with due regard for the requests made by Member States pursuant to paragraph 1a.

Justification

It is essential to have one single Community rolling plan, rather than a superposition of national rolling plans. The Agency should be responsible for developing this draft rolling plan, with due regard for the concerns of Member States.

Amendment 177
Article 43 a bis, paragraph 1 a (new)

1a. Member States may, before 31 January each year, present to the Agency their comments on the content of the draft plan, suggest the inclusion of new substances in the rolling plan and propose that responsibility for an evaluation be awarded to national bodies.

Justification

It is essential to have one single Community rolling plan, rather than a superposition of national rolling plans. The Agency should be responsible for developing this draft rolling plan, with due regard for the concerns of Member States.

Amendment 178
Article 43 a bis, paragraph 2

2. A rolling plan as referred to in ***paragraph 1*** shall cover a period of three years, updated annually, and shall specify the substances ***which the Member State is planning to evaluate*** each year. ***The Member State*** shall submit the rolling plan to ***the Agency and the other*** Member States by 28 February each year. ***The Agency may make comments and Member States may send their comments to the Agency or express their interest in evaluating a substance by 31 March of each year.***	2. A rolling plan as referred to in ***paragraphs 1 and 1a*** shall cover a period of three years, updated annually, and shall specify the substances ***that will be evaluated*** each year ***at Community level by the Agency or, when the case arises, in the Member States that have made a request under Article 43a bis, paragraph 1b***. ***The Agency*** shall submit the ***Community*** rolling plan to ***(deletion) the*** Member States by 28 February each year.

Justification

It is essential to have one single Community rolling plan, rather than a superposition of national rolling plans. The Agency should be responsible for developing this draft rolling

plan, with due regard for the concerns of Member States.

Amendment 179
Article 43 a bis, paragraph 3

3. In cases where there have been no comments on ***a rolling plan or no other Member State has expressed an interest***, ***the Member State*** shall adopt this rolling plan. ***The competent authority shall be the competent authority of the Member State that has included the substance in its definitive rolling plan.***	3. In cases where there have been no comments on ***the Community*** rolling plan, ***the Agency*** shall adopt this rolling plan. ***Otherwise, the Agency shall prepare a new draft rolling plan which shall be submitted to the Member States. If no new comments are made on the content of the Community rolling plan within 30 days, the Agency shall adopt it. If differences of opinion remain, not least in the event of several Member States proposing different bodies for the evaluation of the same substance, the Agency shall submit the rolling plan to the Commission, which shall adopt it in accordance with the procedure referred to in Article 130(3).***

Justification

It is essential to have a single Community rolling plan rather than multiple national rolling plans. The Agency is entrusted with finalising this draft rolling plan, taking into account Member States' concerns.

Amendment 180
Article 43 a bis, paragraph 4

4. In cases where two or more Member States have included the same substance in their draft rolling plans or, after submission of the rolling plans, have expressed an interest in evaluating the same substance, the competent authority for the purposes of Articles 44, 45 and 46 shall be determined in accordance with the procedure laid down in the second, third and fourth subparagraphs.	***deleted***
The Agency shall refer the matter to the Member State Committee provided for in	

***Article** 72(1)(e), hereinafter 'the Member State Committee', in order to agree which authority shall be the competent authority, taking into account the principle that the allocation of substances among Member States shall reflect their proportion of the total Community gross domestic product. Wherever possible, priority shall be given to Member States that have already performed dossier evaluations of the substance in question under Articles 39 to 43.*

If, within 60 days of the referral, the Member State Committee reaches unanimous agreement, the Member States concerned shall adopt their definitive rolling plans accordingly. The competent authority shall be the competent authority of the Member State that has included the substance in its definitive rolling plan.

If the Member State Committee fails to reach a unanimous agreement, the Agency shall submit the conflicting opinions to the Commission, which shall decide which authority shall be the competent authority, in accordance with the procedure referred to in Article 130(3), and the Member States shall adopt their definitive rolling plans accordingly.

Justification

It is essential to have a single Community rolling plan rather than multiple national rolling plans. The Agency is entrusted with finalising this draft rolling plan, taking into account Member States' concerns.

Amendment 181
Article 43 a bis, paragraph 5

5. ***As soon as the competent authorities have been determined, the*** Agency shall publish the definitive rolling plans on its website.	5. ***The*** Agency shall publish the definitive rolling ***plan*** on its website.

Justification

It is essential to have a single Community rolling plan rather than multiple national rolling plans. The Agency is entrusted with finalising this draft rolling plan, taking into account Member States' concerns.

Amendment 182
Article 43 a bis, paragraph 6

6. The competent authority identified in accordance with paragraphs 1 to 4 shall evaluate all substances on its rolling plan in accordance with this Chapter.	***deleted***

Justification

It is essential to have a single Community rolling plan rather than multiple national rolling plans. The Agency is entrusted with finalising this draft rolling plan, taking into account Member States' concerns.

Amendment 183
Article 44, paragraphs 1 and 4

1. If the ***competent authority*** considers that further information is required for the purposes of clarifying the suspicion, referred to in Article 43a *bis* (1), including, if appropriate, information not required in Annexes V to VIII, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information. The decision shall be taken in accordance with the procedure laid down in Articles 48 and 49.	1. If the ***Agency*** considers that further information is required for the purposes of clarifying the suspicion, referred to in Article 43a *bis* (1), including, if appropriate, information not required in Annexes V to VIII, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information. The decision shall be taken in accordance with the procedure laid down in Articles 48 and 49.
4. When the ***competent authority*** finishes its evaluation activities under paragraphs 1, 2 and 3, it shall notify the ***Agency*** accordingly within 12 months of the start of the evaluation of the substance. If this deadline is exceeded, the evaluation shall be deemed to be finished.	4. When the ***Agency*** finishes its evaluation activities under paragraphs 1, 2 and 3, it shall notify the ***Member States*** accordingly within 12 months of the start of the evaluation of the substance. If this deadline is exceeded, the evaluation shall be deemed to be finished.

Justification

Consistency with the SAGE proposal (strengthening the Agency's role in the evaluation phase).

Amendment 184
Article 45, Paragraph 1

(1) The ***competent authority*** shall base its evaluation of a substance on any previous evaluation under this Title. Any draft decision requiring further information under Article 44 may be justified only by a change of circumstances or acquired knowledge.	(1) The ***Agency or the relevant institute*** shall base its evaluation of a substance on any previous evaluation under this Title. Any draft decision requiring further information under Article 44 may be justified only by a change of circumstances or acquired knowledge.

Justification

Linked to amendment of Article 38.

Amendment 185
Article 45, Paragraph 2

(2) ***In order to ensure a harmonised approach to requests for further information, the Agency shall monitor draft decisions under Article 44 and shall develop criteria and priorities.*** Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article 130(3).	(2) Where appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article 130(3).

Justification

Seeks at strengthening the Agency's role in the evaluation of chemicals, while at the same time making the best possible use of the available resources, and especially of the expertise resources already present in the Member States.

Amendment 186
Article 46, paragraphs 1 and 2

1. The ***competent authority*** shall examine any information submitted in consequence of a decision taken under Article 44, and shall draft any appropriate decisions in accordance with Article 44, if necessary.	1. The ***Agency*** shall examine any information submitted in consequence of a decision taken under Article 44, and shall draft any appropriate decisions in accordance with Article 44, if necessary.
2. Once the substance evaluation has been completed, the ***competent authority*** shall use the information obtained from this evaluation for the purposes of Articles 56(3) and 66(2) and shall transmit the information obtained to the Commission, the Agency and the ***other*** Member States. The ***competent authority*** shall inform the Commission, ***the Agency,*** the registrant and the ***competent authorities of the other*** Member States of its conclusions as to whether or how to use the information obtained.	2. Once the substance evaluation has been completed, the ***Agency*** shall use the information obtained from this evaluation for the purposes of Articles 56(3) and 66(2) and shall transmit the information obtained to the Commission and the Member States. The ***Agency*** shall inform the Commission, the registrant and the Member States of its conclusions as to whether or how to use the information obtained.

Justification

Consistency with the SAGE proposal (strengthening the Agency's role in the evaluation phase).

Amendment 187
Article 48, paragraphs 1, 2 and 3 and paragraph 4, point (a)

1. The ***competent authority*** shall communicate any draft decision under Articles 39, 40 or 44 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. The ***competent authority*** shall take any comments received into account and may amend the draft decision accordingly.	1. The ***Agency*** shall communicate any draft decision under Articles 39, 40 or 44 to the registrant(s) or downstream user(s) concerned, informing them of their right to comment within 30 days of receipt. The ***Agency*** shall take any comments received into account and may amend the draft decision accordingly.
2. If a registrant has ceased the manufacture or import of the substance, he shall inform the ***competent authority*** of this fact with the consequence that his registration shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration.	2. If a registrant has ceased the manufacture or import of the substance, he shall inform the ***Agency*** of this fact with the consequence that his registration shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration.
3. The registrant may cease the manufacture or import of the substance upon receipt of the draft decision. In such cases, he shall	3. The registrant may cease the manufacture or import of the substance upon receipt of the draft decision. In such cases, he shall

inform the ***competent authority*** of this fact with the consequence that his registration shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration.	inform the ***Agency*** of this fact with the consequence that his registration shall no longer be valid, and no further information may be requested with respect to that substance, unless he submits a new registration.
(a) where the ***competent authority*** prepares a dossier in accordance with Annex XIV concluding that there is a potential long-term risk to man or the environment justifying the need for further information;	(a) where the ***Agency*** prepares a dossier in accordance with Annex XIV concluding that there is a potential long-term risk to man or the environment justifying the need for further information;

Justification

Consistency with the SAGE proposal (strengthening the Agency's role in the evaluation phase).

Amendment 188
Article 49, Paragraph 1

(1) The ***competent authority of a Member State*** shall ***notify*** its draft decision in accordance with Article 39, 40 or 44 ***to the Agency***, together with any comments by the registrant or downstream user, and specifying how these comments have been taken into account. ***The Agency shall circulate this draft decision, together with the comments, to the competent authorities of the other Member States.***	(1) The ***Agency*** shall ***circulate to the Member States*** its draft decision***, based, where appropriate, on the evaluation carried out by the relevant institute,*** in accordance with Article 39, 40 or 44, together with any comments by the registrant or downstream user, and specifying how these comments have been taken into account.

Justification

Linked to amendment of Article 38.

Amendment 189
Article 49, paragraph 2

2. Within 30 days of circulation, the ***competent authorities of the other*** Member States may propose amendments to the draft decision to the Agency with a copy to the competent authority. ***The Agency may***	2. Within 30 days of circulation, the Member States may propose amendments to the draft decision to the Agency with a copy to the competent authority.

propose amendments to the draft decision within the same period with a copy to the competent authority.

Justification

Consistency with the SAGE proposal (strengthening the Agency's role in the evaluation phase).

Amendment 190
Article 49, paragraphs 3 and 4

3. If the Agency does not receive any proposals ***or does not make any proposal itself*** within 30 days, it shall take the decision in the version notified under paragraph 1.	3. If the Agency does not receive any proposals within 30 days, it shall take the decision in the version notified under paragraph 1.
4. If the Agency receives a proposal for amendment, it may modify the draft decision. The Agency shall refer a draft decision, together with any amendments proposed, to the Member State Committee within 15 days of the end of the 30-day period referred to in paragraph 2. ***The Agency shall do the same if it has made a proposal for amendment in accordance with paragraph 2.***	4. If the Agency receives a proposal for amendment, it may modify the draft decision. The Agency shall refer a draft decision, together with any amendments proposed, to the Member State Committee within 15 days of the end of the 30-day period referred to in paragraph 2.

Justification

Consistency with the SAGE proposal (strengthening the Agency's role in the evaluation phase).

Amendment 191
Article 50, paragraph 1

1. If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study ***equally***.	1. If a registrant or downstream user performs a test on behalf of others, they shall all share the cost of that study. ***The Agency shall establish the cost-sharing criteria on a basis of transparency and proportionality.***

Justification

If proportionate costs are to be determined, the Agency must establish fair criteria. This amendment is linked to the other amendments to articles in Title VI: Evaluation of substances.

Amendment 192
Article 51

Obligations for Member States to report to the Agency	***Publication of information on evaluations***
By 28 February of each year, ***each Member State shall report to*** the Agency on the progress made over the previous calendar year towards discharging the obligations incumbent upon ***the competent authorities within that State*** in relation to the examination of testing proposals. ***The Agency shall publish this information on its web-site without delay.***	By 28 February of each year, the Agency ***shall publish a report on its website*** on the progress made over the previous calendar year towards discharging the obligations incumbent upon ***it*** in relation to the examination of testing proposals.

Justification

Consistency with the SAGE proposal (the role of the European Agency).

Amendment 193
Article 52

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 or that these substances are*** replaced by suitable alternative substances or technologies.	The aim of this Title is to ensure ***that*** substances of very high concern are replaced by suitable alternative substances or technologies ***where available, while ensuring the proper functioning of the internal market.***

Justification

In the authorisation phase, public health and environmental protection objectives take precedence over internal market rules. Furthermore, a clearer link should be established with the principle of substitution.

Amendment 194
Article 53, paragraph 1, points (a) and (b)

1. A manufacturer, importer or downstream user shall not place on the market a substance for a use ***or use it himself*** if that substance is included in Annex XIII, unless:	1. A manufacturer, importer or downstream user shall not place on the market a substance for a use ***in a way which is equivalent to placing it on the market*** if that substance is included in Annex XIII, unless:
(a) the use(s) of that substance on its own, in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been authorised in accordance with Articles 57 to 61; or	(a) the use(s) of***, or the categories of use and exposure categories applicable to,*** that substance on its own, in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself ***in a way which is equivalent to placing it on the market*** has been authorised in accordance with Articles 57 to 61; or
(b) the use(s) of that substance on its own, in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIII itself in accordance with Article 55(2); or	(b) the use(s) of***, or the categories of use and exposure categories applicable to,*** that substance on its own, in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself ***in a way which is equivalent to placing it on the market*** has been exempted from the authorisation requirement in Annex XIII itself in accordance with Article 55(2); or

Justification

The authorisation of a substance does not pertain to its manufacture. The amendment is intended for the purpose of clarification, since otherwise manufacture would become impossible if the manufacturer could not then, for example, store the substance without authorisation.

Amendment 195
Article 53, paragraph 1, point (e)

(e) if the substance is to be placed on the market, the immediate downstream user has been granted authorisation for the use in question.	*(e) if the substance is to be placed on the market, the immediate downstream user has been granted authorisation for the use* ***or category or use and exposure category*** *in question.*

Amendment 196
Article 53, paragraph 2

2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.	2. A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use ***or use and exposure category***.

Justification

Amendment necessitated by the introduction of use and exposure categories. The same applies to Articles 55(1)(c)(ii), 55(1)(d), 58(4), 58(5) and 58(6).

Amendment 197
Article 53, paragraph 5, points (a), (b), (c), (d), (e) and (f)

(a) uses in plant protection products within the scope of Directive 91/414/EEC;	***Deleted***
(b) uses in biocidal products within the scope of Directive 98/8/EC;	
(c) uses as medicinal products for human or veterinary use within the scope of Regulation (EEC) No 2309/93 and Directives 2001/82/EC and 2001/83/EC;	
(d) uses as food additives within the scope of Directive 89/107/EEC;	
(e) uses as additives in animal *feeding stuffs* ***within the scope of Directive 70/524/EEC;***	
(f) uses as flavourings in foodstuffs within the scope of Decision 1999/217/EC;	

Justification

See Article 2. The above substances should not be covered by REACH.

Amendment 198
Article 53, paragraph 5, point (i a) (new)

(ia) substances that do not have to be registered.

Justification

The authorisation procedure should apply to registered substances only. Substances excluded from registration should therefore also be exempted from the authorisation requirement.

Amendment 199
Article 53, Paragraph 7, Introductory part

(7) Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations:	(7) Paragraphs 1 and 2 shall not apply to the use of substances when they are present in preparations ***or articles***:

Justification

Concentration limits should also be included for substances in articles. The proposal's discrimination against substances in articles is not justified by toxicological and eco-toxicological criteria. Furthermore, unlike substances in preparations, exposure to substances in articles requires an extraction medium and thus exposure is further limited. This amendment is in line with current EC legislation on articles.

Amendment 200
Article 53, paragraph 7 a (new)

7a. Paragraph 1 shall not apply to the use of substances on their own, in preparations, or in articles covered by the conditions or restrictions set out in Annex XVI or XVII.

Justification

The proposed additional eighth paragraph of Article 53 makes it clear that decisions already taken by the Council and Parliament under Directive 76/769/EEC, or those to be taken in the future by the Commission under the procedure laid down in Article 130 of the Treaty (comitology), should not be discussed again. Whether and how far substances already subject to legal regulation should be removed from the scope of those provisions should not be left to the judgement of the Commission.

Amendment 201
Article 54, points (a), (b) and (c)

(a) substances ***meeting the criteria for classification*** as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;	(a) substances ***classified*** as carcinogenic category 1 or 2 in accordance with Directive 67/548/EEC;
(b) substances ***meeting the criteria for classification*** as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;	(b) substances ***classified*** as mutagenic category 1 or 2 in accordance with Directive 67/548/EEC;
(c) substances ***meeting the criteria for classification*** as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;	(c) substances ***classified*** as toxic for reproduction category 1 or 2 in accordance with Directive 67/548/EEC;

Justification

Before a substance is authorised, a legally binding decision must be taken on its classification (on the basis of a harmonised classification ruling placing it in CMR categories 1 or 2). Otherwise, the decisions of the Member State Committee(s) responsible for classifying substances in CMR categories 1 and 2 would be invalidated. There must be legal certainty, particularly as regards world trade.

Amendment 202
Article 54, 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) and (e) and which are identified as causing serious and irreversible effects to humans or the environment which are equivalent to those of other substances listed in points (a) to (e) on a case-by-case basis in accordance with the procedure set out in Article 56.	***deleted***

Justification

No criteria exist for the definition of endocrine disrupting properties. Criteria supplementary to those established in Article 54(d) and (e) must be identified on the basis of scientific evidence so as not to give rise to arbitrary decisions. This amendment is linked to the other

amendments to articles in Title VII: Authorisation.

Amendment 203
Article 54 a (new)

Revision of substances to be included in Annex XIII

(1) At the earliest six years following the entry into force of this Regulation, the European Commission shall request that the Scientific Committee on Health and Environmental Risks (SCHER) provide an opinion as to whether additional scientific criteria should be added to Article 54 of this Regulation and its relevant Annexes and shall provide guidance on such criteria.

(2) Based on the opinion of the SCHER and with regard to Article 251 of the Treaty, the Commission may make a proposal to the European Parliament and Council to amend the categories listed in Article 54 to cover other substances posing an equivalent level of concern where their properties:

a) can be established by clear scientific criteria using internationally validated test methods and;

b) are found to cause serious and irreversible adverse effects to human health or the environment.

Justification

This amendment ensures both legal certainty and that the restrictions of the authorisation process focus on substances that have a proven adverse effect on human health or the environment when examined against clearly established scientific criteria validated at international level, such as the OECD.

Amendment 204

Article 55, paragraph 1

1. Whenever a decision is taken to include in Annex XIII substances referred to in Article 54, such a decision shall be taken in accordance with the procedure referred to in Article 130(3). It shall specify for each substance:	1. Whenever a decision is taken to include in Annex XIII substances referred to in Article 54, ***which were previously registered in accordance with Title II,*** such a decision shall be taken in accordance with the procedure referred to in Article 130(3). It shall specify for each substance:

Justification

Only registered substances can undergo an authorisation procedure. Unregistered substances in any case may not be produced or imported. This addition aids clarity.

Amendment 205
Article 55, paragraph 1, point (e)

(e) uses or categories of *uses* exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.	(e) uses or categories of *uses* ***or exposure categories*** exempted from the authorisation requirement, if any, and conditions for such exemptions, if any.

Amendment 206
Article 55, paragraph 2, introductory part

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:	2. Uses or categories of *uses* ***or exposure categories*** may be exempted from the authorisation requirement. In the establishment of such exemptions, account shall be taken, in particular, of the following:

Amendment 207
Article 55, paragraph 4, point (b)

(b) uses which should be exempt from the authorisation requirement.	(b) uses ***or categories of use or exposure categories*** which should be exempt from the authorisation requirement.

Amendment 208
Article 56, paragraph 7

7. If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, the Agency may include that substance in its recommendations under Article 55(3). If the Member State Committee fails to reach a unanimous agreement, it shall adopt an opinion within 30 days of the referral. The Agency shall transmit that opinion to the Commission, including information on any minority view within the Committee.	7. If, within 30 days of the referral, the Member State Committee reaches a unanimous agreement on the identification, the Agency may include that substance in its recommendations under Article 55(3). ***The registrant concerned shall be given the opportunity to state his views in advance.*** If the Member State Committee fails to reach a unanimous agreement, it shall adopt an opinion within 30 days of the referral. ***The registrant concerned shall be given the opportunity to state his views before the opinion is drafted.*** The Agency shall transmit that opinion to the Commission, including information on any minority view within the Committee ***and on the views expressed by the registrants concerned and, if those views have not been incorporated in the opinion, the reasons why not***.

Justification

The Agency's opinion precedes a possible comitology procedure and therefore prejudices the position of the registrants concerned. It is therefore necessary to allow the registrants concerned to be heard before the opinion is drafted.

Amendment 209
Article 57, paragraph 2

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.***	2. An authorisation shall be granted if:
The Commission shall not consider the following:	
(a) risks to human health ***and*** the environment ***of emissions of the*** substance	***(a) the risk*** to human health ***or*** the environment ***from the use of a*** substance

from an installation for which a permit was granted in accordance with Council Directive 96/61/EC;	***arising from the intrinsic properties specified in Annex XIII is adequately controlled in accordance with Annex I, point 6, following the indications provided in the applicant's chemical safety report, and***
(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;	***(b)any necessary measures have been adopted to minimize exposure, and that either***
(c) risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC of the European Parliament and of the Council.	***(c) there are no suitable alternative replacement substances or technologies, or***
	(d) it is shown that the socio-economic benefits outweigh any actual risks to human health or the environment arising from the use of the substance.

Justification

It is appropriate to encourage the substitution of substances of very high concern specified in Annex XIII. These substances should only be authorised as an exception and under specific conditions. It is not sufficient for their use to be 'adequately controlled'.

Amendment 210
Article 57, paragraph 3

3. 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:	***deleted***
(a) the risk posed by the uses of the substance;	

(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties; ***(c) the analysis of the alternatives submitted by the applicant under Article 59(5) and any third party contributions submitted under Article 61(2);*** ***(d) available information on the health or environmental risks of any alternative substances or technologies.***	

Justification

It is appropriate to encourage the substitution of substances of very high concern specified in Annex XIII. These substances should only be authorised as an exception and under specific conditions. It is not sufficient for their use to be 'adequately controlled'.

Amendment 211
Article 57, paragraph 6

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***.	6. Authorisations ***shall*** be subject to conditions, including ***the obligatory submission of monitoring and substitution plans.*** Authorisations shall be subject to ***time limits, with a maximum period of seven years, but maybe renewed according to the provisions set out in Article 58.***

Justification

Substitution and innovation should be encouraged. In addition, authorisations must be subject to time limits (a maximum of five years).

Amendment 212
Article 57, paragraph 7, point (c)

(c) the use(s) for which the authorisation is granted;	(c) the use(s) ***or categories of use or exposure categories*** for which the authorisation is granted;

Amendment 213
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 ***(deletion)*** risk for human health or the environment, the Commission may suspend the authorisation pending the review, taking into account proportionality.

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. This amendment is linked to the other amendments to the articles under Title VII: Authorisation.

Amendment 214
Article 59, paragraph 3

3. Applications may be made for one or several substances, and for one or several uses. Applications may be made for the applicant's own use(s) and/or for uses for which he intends to place the substance on the market.	3. Applications may be made for one or several substances, and for one or several uses ***or categories of use or exposure categories***. Applications may be made for the applicant's own use(s) ***or categories of use or exposure categories*** and/or for uses ***or categories of use or exposure categories*** for which he intends to place the substance on the market.

Amendment 215
Article 59, paragraph 4, point (c)

(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) ***or categories of use or exposure categories*** 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;

Amendment 216
Article 60, paragraph 1

1. If an application has been made for a use of a substance, a subsequent applicant may refer, by means of a letter of access granted by the previous applicant, to the parts of the previous application submitted in accordance with Article 59(4)(d) and (5).	1. If an application has been made for a use ***or category of use or exposure category*** of a substance, a subsequent applicant may refer, by means of a letter of access granted by the previous applicant, to the parts of the previous application submitted in accordance with Article 59(4)(d) and (5).

Amendment 217
Article 60, paragraph 1

2. If an authorisation has been granted for a use of a substance, a subsequent applicant may refer, by means of a letter of access granted by the holder of the authorisation, to the parts of the holder's application submitted in accordance with Article 59(4)(d) and (5).	1. If an authorisation has been granted for a use ***or category of use or exposure category*** of a substance, a subsequent applicant may refer, by means of a letter of access granted by the holder of the authorisation, to the parts of the holder's application submitted in accordance with Article 59(4)(d) and (5).

Amendment 218
Article 61, paragraph 4, points (a) and (b)

(a) Risk Assessment Committee: an assessment of the risk to health and/or the environment arising from the use(s) of the substance as described in the application;	(a) Risk Assessment Committee: an assessment of the risk to health and/or the environment arising from the use(s) ***or categories of use or exposure categories*** of the substance as described in the application;
(b) Socio-economic Analysis Committee: an assessment of the socio-economic factors associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 59(5).	(b) Socio-economic Analysis Committee: an assessment of the socio-economic factors associated with the use(s) ***or categories of use or exposure categories*** of the substance as described in the application, when an application is made in accordance with Article 59(5).

Amendment 219
Article 62

Obligation ***of holders of authorisations***	Obligation ***to provide information on substances subject to authorisation***
Holders of an authorisation shall include the authorisation number on the label	***All substances and preparations which meet the conditions set out in Article 54***

before they place the substance on the market for an authorised use.	***shall be labelled and accompanied, at all times, by a safety data sheet. The label shall indicate:*** ***(a) the name of the substance,*** ***(b) attestation that the substance is included in Annex XIII, and*** ***(c) each specific use for which the substance has been authorised.***

Justification

Hazardous substances and preparations must be labelled so as to provide information to users.

Amendment 220

Article 64, paragraphs 1 and 2

1. A substance ***on its own***, ***in a*** preparation or ***in an*** article***,*** for which Annex XVI contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development, or product and process orientated research and development in quantities not exceeding 1 tonne per year.	1. A substance, preparation or article for which Annex XVI contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance in scientific research and development, or product and process orientated research and development in quantities not exceeding 1 tonne per year.
2. A substance ***on its own***, ***in a*** preparation or ***in an*** article***,*** for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance for laboratory scale research or the use of the substance as a reference standard.	2. A substance, preparation or article for which Annex XVII contains a restriction shall not be manufactured, placed on the market or used unless it complies with the conditions of that restriction. This shall not apply to the manufacture, placing on the market or use of a substance for laboratory scale research or the use of the substance as a reference standard.

Justification

The provisions should not only apply to substances on their own, in preparations or in articles. As under current law (Directive 76/769/EEC), it should also be possible to regulate

dangerous preparations and articles directly. The amendment serves the purpose of clarification, so that such preparations and articles can also be regulated without consideration of their individual components and taking as a basis, instead, the hazardous effect as a whole.

Amendment 221
Article 66, paragraph 1

1. If the Commission considers that the manufacture, placing on the market or use of a substance ***on its own***, ***in a*** preparation or ***in an*** article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed at Community level, it shall ask the Agency to prepare a dossier which conforms to the requirements of Annex XIV. If ***this*** dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Agency shall suggest restrictions, in order to initiate the restrictions process.	1. If the Commission considers that the manufacture, placing on the market or use of a substance, preparation or article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed at Community level, it shall ask the Agency to prepare a dossier which conforms to the requirements of Annex XIV. ***Before compiling the dossier, the Agency shall give the registrants concerned the opportunity to express an opinion.*** If ***the*** dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Agency shall suggest restrictions, in order to initiate the restrictions process.
The Agency shall refer to any Member State dossier, chemical safety report or risk assessment submitted to it under this Regulation. It shall also refer to any relevant risk assessment submitted by third persons for the purposes of other Community Regulations or Directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Agency on request.	The Agency shall refer to any Member State dossier, chemical safety report or risk assessment submitted to it under this Regulation. It shall also refer to ***the opinions of the registrants concerned and*** any relevant risk assessment submitted by third persons for the purposes of other Community Regulations or Directives. To this end other bodies, such as agencies, established under Community law and carrying out a similar task shall provide information to the Agency on request.

Justification

The dossier prepares the ground for a restriction decision, and thus prejudices the position of the registrants concerned. It is therefore necessary to allow the registrants concerned to be heard before the dossier is drafted and, when the dossier is being drafted, to take account of the information provided by the registrants concerned.

Amendment 222
Article 66, paragraph 2, subparagraph 1

2. If a Member State considers that the manufacture, placing on the market or use of a substance ***on its own***, ***in a*** preparation or ***in an*** article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed at Community level, it shall prepare a dossier which conforms to the requirements of Annex XIV. If this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in the format outlined in Annex XIV, in order to initiate the restrictions process.	2. If a Member State considers that the manufacture, placing on the market or use of a substance, preparation or article poses a risk to human health or the environment that is not adequately controlled and needs to be addressed at Community level, it shall prepare a dossier which conforms to the requirements of Annex XIV. If this dossier demonstrates that action on a Community-wide basis is necessary, beyond any measures already in place, the Member State shall submit it to the Agency in the format outlined in Annex XIV, in order to initiate the restrictions process.

Justification

The provisions should not only apply to substances on their own, in preparations or in articles. As under current law (Directive 76/769/EEC), it should also be possible to regulate dangerous preparations and articles directly. The amendment serves the purpose of clarification, so that such preparations and articles can also be regulated without consideration of their individual components and taking as a basis, instead, the hazardous effect as a whole.

Amendment 223
Article 66, Paragraph 2a (new)

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

Justification

Restrictions may apply without tonnage limit i.e. below 1t/y. There is a right to know from the

companies which have registered but also from those which either are not subject to registration (below 1t/y) or are not yet subject owing to the different deadlines applied to the tonnage level.

Amendment 224
Article 69, paragraph 1 a (new)

	1a. Before publishing the opinions, the Agency shall give the registrants concerned the opportunity to be heard.

Justification

The committees' opinions may prejudice the position of the registrants concerned. It is therefore necessary to give them the opportunity to express their views, so that they can be taken into account in the subsequent comitology procedure.

Amendment 225
Article 69, paragraph 2

2. The Agency shall publish the opinions of the two Committees on its website without delay.	2. The Agency shall publish the opinions of the two Committees on its website without delay***, while maintaining the confidentiality required under Article 116***.

Justification

Article 116 also applies here.

Amendment 226
Article 69, paragraph 3

3. The Agency shall provide the Commission on request with all documents and evidence submitted to or considered by it.	3. The Agency shall provide the Commission on request with all documents and evidence submitted to or considered by it. ***It shall also forward the statements received from the registrants concerned.***

Amendment 227

Article 72, paragraph 1, points (c), (d), (e) and (g)

(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 Risk Assessment, which shall be responsible for preparing the opinion of the Agency on ***evaluations,*** 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;
(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 the present Regulation including the socio-economic analysis of the effect of possible legislative action on substances;	(d) a Committee for Socio-economic Analysis, which shall be responsible for preparing the opinion of the Agency on ***evaluations,*** applications for authorisation, proposals for restrictions, and any other questions that arise from the operation of the present Regulation including the socio-economic analysis of the effect of possible legislative action on substances;
(e) a Member State Committee, which shall be responsible for resolving divergences of opinions on draft decisions proposed by ***Member States*** under Title VI and preparing the opinion of the Agency on proposals for classification and labelling under Title X and proposals for identification of substances of very high concern to be subjected to the authorisation procedure under Title VII;	(e) a Member State Committee, which shall be responsible for resolving ***any*** divergences of opinions ***between Member States*** on draft decisions proposed by ***the Agency*** under Title VI and preparing the opinion of the Agency on proposals for classification and labelling under Title X and proposals for identification of substances of very high concern to be subjected to the authorisation procedure under Title VII;
(g) a Secretariat, which shall provide technical, scientific and administrative support for the Committees and the Forum and ensure appropriate co-ordination between them. It shall also undertake the work required of the Agency under the procedures for pre-registration***,*** registration ***and mutual recognition*** of evaluation as well as preparation of guidance, database maintenance and information provision;	(g) a Secretariat, which shall provide technical, scientific and administrative support for the Committees and the Forum and ensure appropriate co-ordination between them. It shall also undertake the work required of the Agency under the procedures for pre-registration ***and*** registration of evaluation as well as preparation of guidance, database maintenance and information provision;

Or. fr

Justification

Consistency with the SAGE proposal (strengthening the Agency's role in the evaluation phase).

Amendment 228
Article 73, paragraph 1

1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of the present Regulation.	1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of the present Regulation. ***In the cases covered by the Regulation, the Agency shall take legally binding decisions.***

Justification

This addition serves to clarify the Agency's role as a decision-taking body, as described in the Commission Communication 'The operating framework for the European Regulatory Agencies' (COM(2002)0718 final).

Amendment 229
Article 73, paragraph 2, point (c a) (new)

	(ca) performing the tasks allotted to it under Title VI;

Justification

Consistency with the SAGE proposal (strengthening the Agency's role in the evaluation phase).

Amendment 230
Article 73, Paragraph 2, Point (f)

(f) providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports by industry and especially by Small and Medium sized Enterprises (SMEs);	(f) providing technical and scientific ***and practical*** guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports by industry and especially by Small and Medium sized Enterprises (SMEs) ***and to assist industry in reaching agreement on the sharing of costs under Title III***;

Justification

This amendment creates an obligation for the Agency to create guidance to help industry in reaching agreement on sharing the costs of data.

Amendment 231
Article 73, paragraph 2, point (i a) (new)

(ia) establishing and maintaining a centre of excellence specialising in risk communication. Providing centralised and co-ordinated resources regarding information on the safe use of chemicals and preparations. Facilitating knowledge-sharing of best practice in the area of risk communication;

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 substances and preparations safely and effectively.

Amendment 232
Article 73, Paragraph 4, Point (f)

(f) ***developing an electronic information exchange procedure;***	(f) ***provide technical and scientific guidance and tools, including a dedicated help-desk and a website, for the operation of this regulation, in particular in order to assist the development of chemical safety reports by industry and especially by Small and Medium Size Enterprises (SMEs);***

Justification

Replaces the relevant part of amendment 74 of the draft report. Specific measures to assist SMEs should be put in place.

Amendment 233
Article 73, Paragraph 4, Point (g a) (new)

	(ga) promote, in cooperation with the Commission, mutual recognition between the EU and third countries of the results of the tests carried out in application of and in conformity with this Regulation;

Justification

Addition to amendment 74 in the draft report. With a view to make use of all the information available on chemicals, including from third countries, and therefore avoid unnecessary tests, mutual recognition of test results should be promoted.

Amendment 234
Article 74, point d

d) the fee structure of the Agency	d) the fee structure of the Agency***, on a transparent and proportionate basis***

Justification

The fee structure should be established on the basis of criteria intended to ensure a distribution that is fair, transparent and, above all, proportionate to costs, given that it is an important instrument for the funding of REACH. This amendment should be read in conjunction with the other amendments tabled to the articles contained in Title IX: The Agency.

Amendment 235
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 from Member States nominated by the Commission and ten representatives nominated by the Council, in consultation with the European Parliament, of whom four shall be chosen on an equal basis on the grounds of their experience in associations representing consumers, industry and SMEs.***

Justification

The membership of the Management Board needs to be carefully balanced (cf. recital 74 of

the REACH proposal). It is essential to involve all the institutions: hence the insertion of consultation of the EP. Equally, it is important to ensure the permanent presence of members chosen, on an equal basis, from consumers' associations, (large-scale) industry and SMEs - in other words, all the participants in the chemicals sector. This amendment should be read in conjunction with the other amendments tabled to the articles contained in Title IX: The Agency.

Amendment 236
Article 79, Paragraph 2, Point (j a) (new)

(ja) adopting the draft and definitive rolling plans of evaluation of substances and its updates pursuant to Title VI, if there are no proposals for amendments.

Justification

Linked to amendment of Article 38.

Amendment 237
Article 81, Paragraph 4, Subparagraph 4

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. ***Stakeholders may also be invited to attend meetings as observers, as appropriate, at the request of the Committee members, or the Management Board.***	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. ***Stakeholders may also attend meetings as observers***.

Justification

The industry needs to be represented at the committee's meetings by more than guests alone. Representatives of the industry and/or SMEs should have observer status. This amendment should be read in conjunction with the other amendments tabled to the articles contained in Title IX: The Agency.

Amendment 238
Article 82, Paragraph 1, Subparagraph 4

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.***

Justification

The industry needs to be represented at the committee's meetings by more than guests alone. Representatives of the industry and/or SMEs should have observer status. This amendment should be read in conjunction with the other amendments tabled to the articles contained in Title IX: The Agency.

Amendment 239
Article 83, Paragraph 2

2. Member States shall transmit to the Agency the names of experts with proven experience in reviewing chemical risk assessments and/or socio-economic analyses or other relevant scientific expertise, 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 reviewing chemical risk assessments and/or socio-economic analyses or other relevant scientific expertise, 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

The experts should be scientifically and politically independent. A procedure should be established for identifying independent experts. This amendment should be read in conjunction with the other amendments tabled to articles contained in Title IX: The Agency.

Amendment 240
Article 83, paragraph 2 a (new)

	2a. On a proposal from the Executive Director, the Management Board shall draw up and make public a list of the competent bodies appointed by the Member

	States which, either individually or as part of a network, may assist the Agency in the performance of its tasks, in particular those conferred on it by Title VI. The Agency may confer certain tasks on these bodies, in particular the evaluation of testing proposals, dossiers and substances.

Justification

It is appropriate to draw up a list of bodies appointed by the Member States to assist the Agency in the performance of its tasks. See the amendment to Article 38.

Amendment 241
Article 83, paragraph 3

3. The provision of services by Committee members or any expert serving on a working group of the Committees or Forum, or performing any other task for the Agency shall be governed by a written contract between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.	3. The provision of services by ***member bodies on the public list referred to in paragraph 2a,*** Committee members or any expert serving on a working group of the Committees or Forum, or performing any other task for the Agency shall be governed by a written contract ***between the Agency and the body concerned,*** between the Agency and the person concerned, or where appropriate between the Agency and the employer of the person concerned.
The person concerned, or his employer, shall be remunerated in accordance with a scale of fees to be included in the financial arrangements established by the Management Board. Where the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration.	***The body,*** the person concerned, or his employer, shall be remunerated in accordance with a scale of fees to be included in the financial arrangements established by the Management Board. Where ***the body or*** the person concerned fails to fulfil his duties, the Executive Director has the right to terminate or suspend the contract or withhold remuneration.

Justification

It is appropriate to draw up a list of bodies appointed by the Member States to assist the Agency in the performance of its tasks. See the amendment to Article 38.

Amendment 242
Article 85, Paragraph 1

1. The Board of Appeal shall consist of a Chairman and two other members.	1. The Board of Appeal shall consist of a ***judge as*** Chairman and two other members.

Justification

In view of the tasks performed by the Board of Appeal, it must be chaired by a judge. This amendment should be read in conjunction with the other amendments tabled to articles contained in Title IX: The Agency.

Amendment 243
Article 85, paragraph 3

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.	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. ***One of the members must be eligible to hold a post as a judge.***

Justification

In view of the tasks of the Board of Appeal, one member should be eligible for a post as a judge.

Amendment 244
Article 87, paragraph 1

1. An appeal may be brought against decisions of the Agency ***taken pursuant to Article 7, Article 18, the third subparagraph of Article 25(4), the first subparagraph of Article 28(2), Article 49, Article 115(4) or Article 116***.	1. An appeal may be brought against decisions of the Agency.

Justification

There must be a basic principle that the right of appeal applies to every decision taken by the

Agency.

Amendment 245
Article 109, Point b

(b) substances within the scope of Article 1 of Directive 67/548/EEC, which meet the criteria for classification as dangerous in accordance with that Directive, and which are placed on the market either on their own, or in a preparation above the concentration limits specified in Directive 1999/45/EC which results in the classification of the preparation as dangerous.	b) substances within the scope of Article 1 of Directive 67/548/EEC, which meet the criteria for classification as dangerous in accordance with that Directive, and which are placed on the market ***in quantities exceeding 100 kg per manufacturer or importer,*** either on their own or in a preparation above the concentration limits ***for effects damaging to health or the environment*** specified in Directive 1999/45/EC which results in the classification of the preparation as dangerous..

Justification

A minimum quantity needs to be established, to avoid minute quantities being reported. Directive 1999/45/EC does not lay down concentration thresholds for Phys-Chem effects. This amendment should be taken in conjunction with the other amendments tabled to the articles of Title X: Classification and Labelling Inventory.

Amendment 246
Article 114, paragraph 1

1. Every ***ten*** years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement in the format specified by Article 108.	1. Every ***two*** years, Member States shall submit to the Commission a report on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement in the format specified by Article 108. ***Reports should include information on monitoring and control measures applied, any infringements identified and penalties imposed, and any problems with implementing the Regulation.***
However, the first report shall be submitted ***five*** years after the entry into force of this Regulation.	However, the first report shall be submitted ***one year*** after the entry into force of this Regulation.

Justification

If the Regulation is to be implemented uniformly, the Member States must report at much shorter intervals. This is the only way that deficiencies can be corrected at an early stage. There should also be minimum requirements for the content of reports, to ensure their quality.

Amendment 247
Article 114, paragraph 2

2. Every ***ten*** years, the Agency shall submit to the Commission a report on the operation of this Regulation.	2. Every ***two*** years, the Agency shall submit to the Commission a report on the operation of this Regulation.
However, the first report shall be submitted ***five*** years after the date of the notification required under Article 131(2).	However, the first report shall be submitted ***two*** years after the date of the notification required under Article 131(2).

Justification

If the Regulation is to be implemented uniformly, the Agency also must report at much shorter intervals. This is the only way that deficiencies can be corrected at an early stage.

Amendment 248
Article 114, paragraph 3

3. Every ***ten*** years, the Commission shall publish a general report on the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1 and 2.	3. Every ***two*** years, the Commission shall publish a general report on the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1 and 2.
However, the first report shall be published six years after the date of the notification required under Article 131(2).	However, the first report shall be published six years after the date of the notification required under Article 131(2).

Justification

Since the Regulation is intended to establish uniformity, ten-yearly reporting periods are too long. CEFIC considers that a system of annual reporting should be introduced.

Amendment 249
Article 115 a (new)

115a. Special provisions on information for

	the public:
	In order to help consumers use substances and preparations safely and sustainably, manufacturers shall provide information on risks by means of an on-pack label on each unit placed on the market for sale to consumers. That label must identify the risks associated with the substance, preparation or product, provide recommendations for the use thereof and specify situations in which the substance, preparation or product should not be used. Furthermore, the labelling should be supplemented where necessary by the use of other means of communication, such as websites, in order to provide more detailed information on the safety and use of substances or preparations.
	Directives 1999/45/EC and 1967/548/EEC must be amended accordingly.

Justification

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

Amendment 250
Article 116, paragraph 1

1. The following information shall not be considered as confidential:	1. The following information shall not be considered as confidential***, unless there are reasons for doing so in the specific case of the manufacturer or importer***:

Justification

It must be permissible in individual cases to make exceptions to the rule that certain information is not confidential. In these exceptional cases, the manufacturer or importer must have the option of giving reasons to justify confidential treatment even for the information listed at Article 116(1).

Amendment 251
Article 116, Paragraph 1

The following information shall not be considered as confidential:	The following information shall not be considered as confidential***, unless otherwise demonstrated by the manufacturer or importer, and unless there are public interest reasons to the contrary:***

Justification

It must be permissible in individual cases to classify certain information as confidential.

Amendment 252
Article 116, paragraph 1, point (a)

(a) the trade name(s) of the substance;	***Deleted***

Justification

The trade name of a substance could constitute sensitive information where other market players were concerned, since it might enable market dealings between manufacturers and customers to be deduced. This information should be classed as confidential under paragraph 2.

Amendment 253
Article 116, paragraph 1, point (b)

(b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC;	(b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC***, unless different provisions under Annex Ia of this Regulation or Article 15 of Directive 1999/45/EC are applicable***;

Justification

Consistency with the requirements of the safety data sheet and existing rules on classification and labelling.

Amendment 254
Article 116, paragraph 1, point (c)

(c) if applicable, the name of the substance as given in Einecs;	(c) if applicable, the name of the substance as given in Einecs***, if it is a dangerous substance within the meaning of Directive 67/548/EEC, unless different provisions under Annex Ia of this Regulation or***

	Article 15 of Directive 1999/45/EC are applicable;

Amendment 255
Article 116, paragraph 1, point (i)

(i) the information contained in the safety data sheet, except for the name of the company/undertaking or where the information is considered confidential by application of paragraph 2;	***Deleted***

Justification

The safety data sheet often contains information intended only for the direct customer, such as detailed indications regarding use. These indications must absolutely be treated as confidential under Article 116(2).

Amendment 256
Article 116, paragraph 2, introductory part

2. The following information shall be considered as confidential***, even if no declaration in accordance with Article 115(2) is made***:	2. The following information shall be considered as confidential:

Justification

The information under points (b) and (c) of the Commission proposal must be 'non-confidential' to enable the necessary studies on the spread of these substances to be carried out, estimates to be made of the quantities distributed and potential exposures to be anticipated.

Amendment 257
Article 116, paragraph 2, point (-a) (new)

	(-a) the name and address of the registrant and any other declarant;

Justification

Manufacturers, importers, and downstream users will almost invariably make a declaration under Article 115(2). The amendment proposed would avoid that expenditure of effort.

Amendment 258
Article 116, paragraph 2, points (c)

(c) the precise tonnage of the substance or preparation manufactured or placed on the market;	***deleted***

Justification

The information under point (c) of the Commission proposal must be 'non-confidential' to enable the necessary studies on the spread of these substances to be carried out, estimates to be made of the quantities distributed and potential exposures to be anticipated.

Amendment 259
Article 116, Paragraph 3

3. All other information shall be accessible in accordance with Article 115.	3. All other information shall be accessible in accordance with Article 115***, except information to be treated as confidential under Article 7(9) and information compiled on given types of isolated intermediates (Article 47)***.

Justification

Registration information on product- and process-orientated research and development must also be equated with mandatory confidential information under Article 116(2) and may not be made accessible as a result of a decision taken in an isolated instance. Intermediates should likewise not be made public, because competitors can easily identify them.

Amendment 260
Article 117

Notwithstanding Articles 115 and 116, information received by the Agency under this Regulation may be disclosed to any government or ***body*** of a third country or an international organisation in accordance with an agreement concluded between the Community and the third party concerned	Notwithstanding Articles 115 and 116, information received by the Agency under this Regulation may be disclosed to any government or ***government institution*** of a third country or an international ***government*** organisation in accordance with an agreement concluded between the

under Regulation (EC) No 304/2003 of the European Parliament and of the Council[1] or under Article 181a (3) of the Treaty, provided that both the following conditions are met:	Community and the third party concerned under Regulation (EC) No 304/2003 of the European Parliament and of the Council[1] or under Article 181a (3) of the Treaty, provided that both the following conditions are met:
a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;	a) the purpose of the agreement is ***government*** cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;

Justification

In order to prevent the fraudulent use of information, it should be clearly established that Article 117 (cooperation) only concerns national and international government bodies. This amendment should be taken in conjunction with the other amendments tabled to the articles of Title XI: Information.

Amendment 261
Article 120

The competent authorities of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment.	***In accordance with the guidelines to be drawn up by the Agency, the*** competent authorities of the Member States shall inform the general public about the risks arising from substances where this is considered necessary for the protection of human health or the environment.

Justification

Guidelines should be drawn up to ensure uniformity in the way the Member States' national authorities inform the public.

Amendment 262
Article 122

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

To enable REACH to be implemented consistently, the Agency's position must be strengthened; to that end, the Agency should be entitled to require Member States to carry out particular checks and activities.

Amendment 263
Article 122, subparagraph 1a (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

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. This amendment should be taken in conjunction with the other amendments tabled to the articles of Title XIII: Enforcement.

Amendment 264
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***, on the basis of a set of guidelines drawn up by the Agency,*** 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 ***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

To leave the system of penalties to the Member States' discretion alone 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. This amendment should be taken in conjunction with the other amendments tabled to the articles of Title XIII: Enforcement.

Amendment 265
Article 125

Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance**,** on its own, ***in*** a preparation or ***in*** an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.	Member States shall not prohibit, restrict or impede the manufacturing, import, placing on the market or use of a substance on its own, a preparation**,** or an article, falling within the scope of this Regulation, which complies with this Regulation and, where appropriate, with Community acts adopted in implementation of this Regulation.

Justification

The Regulation's provisions should not apply only to substances, either alone or in preparations or articles. As under existing law (Directive 76/769/EEC) it must also be possible to regulate dangerous preparations and articles directly. This amendment serves to clarify that Article 125 applies to such cases too.

Amendment 266
Article 126, Paragraph 1

1. Where a Member State has justifiable grounds for believing that a substance**,** on its own, ***in*** a preparation or ***in*** an article, although satisfying the requirements of this Regulation, constitutes a risk to human health or the environment, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based.	1. Where a Member State has justifiable grounds for believing that a substance on its own, a preparation**,** or an article, although satisfying the requirements of this Regulation, constitutes a risk to human health or the environment, it may take appropriate provisional measures. The Member State shall immediately inform the Commission, the Agency and the other Member States thereof, giving reasons for its decision and submitting the scientific or technical information on which the provisional measure is based.

Justification

The Regulation's provisions should not apply only to substances, either alone or in preparations or articles. As under existing law (Directive 76/769/EEC) it must also be possible to regulate dangerous preparations and articles directly. This amendment serves to clarify that Article 125 applies to such cases too.

Amendment 267
Article 132 a (new)

Intermediary ex post-impact assessment

(1) Five years after the entry into force of the present Regulation, without prejudice to the provisions of Article 133, the Commission shall carry out an intermediary ex post-impact assessment of the present Regulation. The post-impact assessment shall analyse the state of play of the implementation of the present Regulation, shall confront the achieved results with the previous expectations, and shall evaluate the impact of the present Regulation on the functioning of the internal market and of the competition thereon.

(2) The Commission shall submit the ex post-impact assessment to the European Parliament and the Council on [sixth anniversary of the entry into force of the present Regulation] at the latest. The Commission shall introduce a proposal for the amendments to the present Regulation that appear necessary on the basis of the ex post-impact assessment.

Justification

Considering the importance of the regulatory system REACH sets up, it is necessary to evaluate the results achieved in the first years of implementation in order to check whether the initial targets can be met, and if not, to make the necessary adjustments.

Amendment 268
Article 134, paragraph 1

Directives 76/769/EEC, 91/157/EEC, 93/67/EEC, 93/105/EEC and 2000/21/EC, and Regulations (EEC) No 793/93 and (EC) No 1488/94 are repealed.	Directives 76/769/EEC, ***91/155/EEC,*** 91/157/EEC, 93/67/EEC, 93/105/EEC and 2000/21/EC***, 2002/95/EC and 2004/37/EC*** and Regulations (EEC) No 793/93 and (EC) No 1488/94 are repealed.

Justification

Duplication of rules should be avoided. The amendments to the previous articles make it possible to dispense with the above directives and regulations.

Amendment 269
Article 135

Article 14 of Directive 1999/45/EC is deleted.	Article 14 of Directive 1999/45/EC is deleted. ***Directive 1999/45/EC shall be amended to ensure consumers are provided with the information needed to take appropriate measures for the safe use of substances and preparations.***

Justification

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

Amendment 270
Article 135 c (new), Title

	Amendment of Directive 89/106/EEC

Amendment 271
Article 135 c (new), paragraph 1

	The following words are added to Article 1(1) of Directive 89/106/EEC:
	'Building products shall not be covered by the requirements of this directive relating to hygiene, health and environmental protection if Regulation (EC) No xxx (REACH Regulation) imposes obligations with regard to these matters.'.'

Justification

To clarify the fact that REACH takes priority and avoid duplication.

Amendment 272
Article 135 d (new), Title

Amendment of Directive 2000/53/EC

Amendment 273
Article 135 d (new), paragraph 1

Article 4(2) and Annex II of Directive 2000/53/EC are deleted.

Justification

Annex XVI of the REACH Regulation lays down uniform rules on restrictions. Different restrictions in different texts should be avoided.

Amendment 274

Annex I, Point 0.2.

0.2. The chemical safety assessment shall address all the identified uses. It shall consider the use of the substance on its own (including any major impurities and additives), in a preparation or in an article. The assessment shall consider all stages of the life-cycle of the substance as defined by the identified uses. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance.	0.2. The chemical safety assessment shall address all the identified uses ***in quantities of 1 tonne or more per year***. It shall consider the use of the substance on its own (including any major impurities and additives), in a preparation or in an article. The assessment shall consider all stages of the life-cycle ***(including the waste phase, notwithstanding Article 2(1)(d) of this Regulation)*** of the substance as defined by the identified uses. The chemical safety assessment shall be based on a comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance.

Or. en

Justification

First Part: see amendment on Article 13.

Second Part: see amendment on Article 2, Paragraph 1 (e).

Amendment 275
Annex I, Point 0.6.

0.6 The main element of the exposure part of the chemical safety report is the description of the manufacturer's or importer's exposure scenario(s) and the exposure scenario(s) recommended by the manufacturer or importer to be implemented for the identified use(s). ***The*** exposure scenarios contain a description of the risk management measures which the manufacturer or importer has implemented and recommends to be implemented by downstream users. If the substance is placed on the market, these exposure scenarios including the risk management measures shall be summarised in an annex to the safety data sheet in accordance with Annex IA.	0.6 The main element of the exposure part of the chemical safety report is the description of the manufacturer's or importer's ***use and exposure categories or*** exposure scenario(s) and the ***use and exposure categories or*** exposure scenario(s) recommended by the manufacturer or importer to be implemented for the identified use(s). ***Use and exposure categories contain a general description of risk management measures, while*** exposure scenarios contain a ***concrete and detailed*** description of the risk management measures which the manufacturer or importer has implemented and recommends to be implemented by downstream users. If the substance is placed on the market, these exposure scenarios including the risk management measures shall be summarised in an annex to the safety data sheet in accordance with Annex IA.

Justification

Amendment following on from the introduction of use and exposure categories. Both should be permissible: a risk description of individual exposure scenarios with detailed description of conditions of use and risk management measures, and a general risk description for each relevant use and exposure category.

Amendment 276
Annex I, Point 0.7.

0.7. The ***level of detail required in describing*** an exposure scenario will vary substantially from case to case, depending on the use of a substance, its hazardous	0.7 The ***detailed description of*** an exposure scenario will vary substantially from case to case, depending on the use of a substance, its hazardous properties and the amount of

properties and the amount of information available to the manufacturer or importer. ***Exposure scenarios can describe the appropriate risk management measures for several individual uses of a substance. Single exposure scenarios may thereby cover large ranges of uses.***	information available to the manufacturer or importer. ***Use and exposure categories provide a structure and description for the general conditions of use and exposure which may apply to several uses.***

Justification

A clear distinction needs to be drawn between an exposure scenario, which constitutes a detailed description of the risk management measures and conditions of use, and use and exposure categories which cover a broad spectrum of uses or applications.

Amendment by Hartmut Nassauer

Amendment 277
Annex I, Point 0.8.

0.8. The process which the manufacturer or importer goes through, in carrying out their chemical safety assessment and developing their chemical safety reports, may be iterative. Iterations may consider on the one hand developing and revising the exposure scenario(s), which may include developing and implementing or recommending risk management measures, and on the other hand the need to generate further information. ***The purpose of generating further information is to establish a more precise risk characterisation, based on a refined hazard assessment or exposure assessment. This will allow appropriate information to be communicated down the supply chain in the safety data sheet.***	0.8. The process which the manufacturer or importer goes through, in carrying out their chemical safety assessment and developing their chemical safety reports, may be iterative. Iterations may consider on the one hand developing and revising ***the use and exposure categories or*** the exposure scenario(s), which may include developing and implementing or recommending risk management measures, and on the other hand the need to generate further information.

Or. de

Justification

Amendment following on from the introduction of use and exposure categories.

Amendment 278
Annex I, Point 0.12.

0.12. Part A of the chemical safety report shall include a declaration that the risk management measures outlined in the relevant exposure scenarios for the manufacturer's or importer's own use(s) are implemented by the manufacturer or importer and that those ***exposure scenarios*** for the identified uses are communicated to all known users further down the supply chain in the safety data sheet.	0.12. 0.12. Part A of the chemical safety report shall include a declaration that the risk management measures outlined in the relevant ***use and exposure categories or*** exposure scenarios for the manufacturer's or importer's own use(s) are implemented by the manufacturer or importer and that those ***use and exposure categories*** for the identified uses are communicated to all known users further down the supply chain in the safety data sheet.

Justification

Amendment following on from the introduction of use and exposure categories. In the substance safety report, reference should in principle be made to the use and exposure categories. In the safety data sheet, only the use and exposure categories should be stated.

Amendment 279
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	1.4.1. Based on the outcomes of steps 1 to 3, a Derived No-Effect Level(s) shall be established for the substance ***for each relevant use and exposure category,*** reflecting ***the intended*** route(s)***,*** duration and frequency of exposure. However, taking into account the available data and the ***use and exposure categories or*** 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 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 established the DNEL, the following factors shall, *inter alia*, be taken into account:	substance for which the DNEL is valid. If more than one route of exposure is ***present***, then a DNEL shall be established for each route of exposure and for the exposure from all routes combined. When established the DNEL, the following factors shall, *inter alia*, be taken into account:

Justification

Amendment following on from the introduction of use and exposure categories. It needs to be made clear that a DNEL must be established for each intended use and exposure category, irrespective of likelihood.

Amendment 280
Annex I, Point 3.3.1.

3.3.1. Based on the available data, the PNEC ***for each environmental sphere*** shall be established. The PNEC may be calculated by applying an appropriate assessment factor to the effect values (e.g. LC50 or NOEC) derived from tests on organisms. An assessment factor expresses the difference between effects values derived for a limited number of species from laboratory tests and the PNEC for the environmental sphere	3.3.1. Based on the available data, the PNEC shall be established ***for each relevant use and exposure category per environmental sphere***. The PNEC may be calculated by applying an appropriate assessment factor to the effect values (e.g. LC50 or NOEC) derived from tests on organisms. An assessment factor expresses the difference between effects values derived for a limited number of species from laboratory tests and the PNEC for the environmental sphere.

Justification

Amendment following on from the introduction of use and exposure categories.

Amendment 281
Annex I, Point 4.2.

4.2. If the substance fulfils the criteria an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. In particular it shall contain an estimation of the amounts of the substance released to the	4.2. If the substance fulfils the criteria an emission characterisation shall be conducted comprising the relevant parts of the exposure assessment as described in Section 5. In particular it shall contain an estimation of the amounts of the substance released to the

different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses, and an identification of the likely routes by which humans and the environment are exposed to the substance.	different environmental compartments during all activities carried out by the manufacturer or importer and all identified uses ***in quantities of 1 tonne or more per year***, and an identification of the likely routes by which humans and the environment are exposed to the substance.

Justification

See amendment on Article 13.

Amendment 282
Annex I, Point 5.1.

5.1. Step 1: ***Development*** of exposure scenarios	5.1. Step 1: ***Establishment*** of ***use and exposure categories or*** exposure scenarios
5.1.1. ***E***xposure scenarios shall be ***developed*** for manufacture in the Community, manufacturer's and importer's own use, and all identified uses. An exposure scenario is the ***set of*** conditions ***that describe*** how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. ***These exposure scenarios may be as wide-ranging or specific as necessary.*** The exposure scenario shall be presented under the relevant heading of the chemical safety report***, and summarised in an annex to the safety data sheet, using an appropriate short title giving a brief general description of the use***. In particular, an exposure scenario includes, where relevant, a description of:	5.1.1. ***Use or exposure categories or e***xposure scenarios shall be ***established*** for manufacture in the Community, manufacturer's and importer's own use, and all identified uses. ***The use and exposure categories shall describe the general conditions of use, measures and instructions for the protection of humans and the environment which are appropriate to meet the prescribed DNELs and PNECs.*** An exposure scenario is the ***description of the specific*** conditions ***setting out*** how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment ***by means of specific protection measures***. The exposure scenario shall be presented under the relevant heading of the chemical safety report. In particular, an exposure scenario includes, where relevant, a description of:

Justification

Amendment following on from the introduction of use and exposure categories. In principle only use and exposure categories should be established. The general measures for the protection of humans and the environment for these categories should be set out and

communicated to customers in the safety data sheet. Exposure scenarios set out specific conditions of use and measures. (Translator's note: Last sentence of justification refers to Amendment 829, not applicable to EN)

Amendment 283
Annex I, Point 5.1.2.

does not apply to EN text

Amendment 284
Annex I, Point 5.2.

5.2. Step 2: ***Exposure*** Estimation	5.2. Step 2: Estimation ***or establishment of exposure***
5.2.1. The exposure shall be estimated for each exposure scenario developed and shall be presented under the relevant heading of the chemical safety report ***and where required and in accordance with Article 29, summarised in an annex to the safety data sheet.*** The exposure estimation entails three elements: (1) emission estimation; (2) chemical fate and pathways; and (3) estimation of exposure levels.	5.2.1. The exposure shall be estimated ***or established*** for each ***use or exposure category or each*** exposure scenario developed and shall be presented under the relevant heading of the chemical safety report . The ***establishment of*** estimation ***of exposure*** entails three elements: (1) ***establishment or*** estimation ***of emission***; (2) chemical fate and pathways; and (3) ***establishment or*** estimation of exposure levels.

Justification

The specific establishment of exposures / emissions should be included and should take precedence over estimates. Exposure estimation models should only be used where no concrete measurement data are available (reality takes precedence over uncertain model observations).

Amendment 285
Annex I, Point 5.2.2. and 5.2.4.

5.2.2. . The ***emission*** estimation shall consider the emissions during all relevant	5.2.2. The ***establishment or*** estimation ***of emission*** shall consider the emissions during

parts of the life-cycle of the substance under the assumption that the risk management measures described in the exposure scenario have been implemented. .	all relevant parts of the life-cycle of the substance under the assumption that the risk management measures described in the ***use and exposure categories or in the*** exposure scenario have been implemented.
5.2.4. ***An estimation of t***he exposure levels shall be ***performed*** for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is ***known or reasonably foreseeable***. Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes of exposure) shall be addressed. Such estimations shall take account of spatial and temporal variations in the exposure pattern. In particular, the exposure estimation shall take account of:	5.2.4. ***T***he exposure levels shall be ***established or estimated*** for all human populations (workers, consumers and humans liable to exposure indirectly via the environment) and environmental spheres for which exposure to the substance is ***intended on the basis of the identified uses and is likely given proper use.*** Each relevant route of human exposure (inhalation, oral, dermal and combined through all relevant routes of exposure) shall be addressed. Such estimations shall take account of spatial and temporal variations in the exposure pattern. In particular, the exposure estimation shall take account of:

Justification

Amendment following on from the introduction of use and exposure categories. Where concrete figures for exposures or emissions are available, they should be used and given clear precedence over estimations. Estimations (derived from models) should only be used when no concrete measurement data are available.

Amendment 286
Annex I, Point 5.2.2., Hyphen 8 and 9

- the ***likely*** routes of exposure of and potential for absorption in humans,	- the routes of exposure of and potential for absorption in humans,
- the ***likely*** pathways to the environment and environmental distribution and degradation and/or transformation (see also Section 3 Step 1)..	- the pathways to the environment and environmental distribution and degradation and/or transformation (see also Section 3 Step 1)

Justification

Amendment following on from the introduction of use and exposure categories. Where concrete figures for exposures or emissions are available, they should be used and given clear precedence over estimations. Estimations (derived from models) should only be used when no concrete measurement data are available.

Amendment 287
Annex I, Point 5.2.5.

5.2.5. Where adequately measured representative exposure data are available, ***special consideration*** shall be given to them when conducting the exposure assessment. Appropriate models can be used for the estimation of exposure levels. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties ***can*** also be considered. .	5.2.5. Where adequately measured representative exposure data are available, ***precedence*** shall be given to them when conducting the exposure assessment. Appropriate models can be used for the estimation of exposure levels. Relevant monitoring data from substances with analogous use and exposure patterns or analogous properties ***shall*** also be considered.

Justification

Amendment following on from the introduction of use and exposure categories. Where concrete figures for exposures or emissions are available, they should be used and given clear precedence over estimations. Estimations (derived from models) should only be used when no concrete measurement data are available.

Amendment 288
Annex I, Point 6.1. and 6.2.

6.1. The risk characterisation shall be carried out for each exposure scenario and shall be presented under the relevant heading of the Chemical Safety Report.	6.1. The risk characterisation shall be carried out for ***each use and exposure category and*** each exposure scenario and shall be presented under the relevant heading of the Chemical Safety Report.
6.2. The risk characterisation shall consider the human populations (exposed as workers, consumers or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is ***known or reasonably foreseeable***, under the assumption that the risk management measures described in the exposure scenarios in the previous Section have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for all relevant spheres and all relevant	6.2. The risk characterisation shall consider the human populations (exposed as workers, consumers or indirectly via the environment and if relevant a combination thereof) and the environmental spheres for which exposure to the substance is ***intended on the basis of the identified uses and is likely given proper use,*** under the assumption that the risk management measures described in the exposure scenarios in the previous Section have been implemented. In addition, the overall environmental risk caused by the substance shall be reviewed by integrating the results for all relevant spheres and all relevant emission/release sources of the

emission/release sources of the substance.	substance.

Justification

Amendment following on from the introduction of use and exposure categories. Furthermore the risk characterisation should relate only to actually intended exposures which are likely on the basis of the identified use supported by the manufacturer or downstream user, given proper use.

Amendment 289
Annex I, Point 6.4., opening clause and Hyphen 1

6.4. For any exposure scenario, the exposures of humans and the environment can be considered to be adequately controlled, if:	6.4 For any ***use and exposure category and any*** exposure scenario, the exposures of humans and the environment can be considered to be adequately controlled, if:
- the exposure levels estimated in Section 6.2 do not exceed the appropriate Dnel or the Pnec, as determined in Sections 1 and 3, respectively, and;	- the exposure levels ***established or*** estimated in Section 6.2 do not exceed the appropriate Dnel or the Pnec, as determined in Sections 1 and 3, respectively, and;

Justification

Amendment following on from the introduction of use and exposure categories. Furthermore the risk characterisation should relate only to actually intended exposures which are likely on the basis of the identified use supported by the manufacturer or downstream user, given proper use.

Amendment 290
Annex I, Point 6.5, first subparagraph.

6.5. For those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the ***exposure scenario*** shall be carried out.	For those human effects and those environmental spheres for which it was not possible to determine a DNEL or a PNEC, a qualitative assessment of the likelihood that effects are avoided when implementing the ***risk management measures*** shall be carried out.

Justification

Amendment following on from the introduction of use and exposure categories. Furthermore the risk characterisation should relate only to actually intended exposures which are likely on

the basis of the use stated and supported by the manufacturer or downstream user, on the assumption of proper use.

Amendment 291
Annex I, Point 7, 5.1., Title

5.1. [Title of Exposure Scenario 1]	5.1. [Title of ***use and exposure category or*** Exposure Scenario 1]

Justification

Amendment following on from the introduction of use and exposure categories..

This amendment also affects the titles of sub-points 5.2.1., 8.2., 8.3.1,. 6.1 and 6.2 .

Amendment 292
Annex Ia, Point 1.2.

Indicate the uses of the substance or preparation as far ***as they are known***. ***Where there are many possible uses, only the most important or common uses need be listed. This shall include a brief description of what it actually does, e.g. flame retardant, anti-oxidant, etc.***	Indicate the ***intended*** uses of the substance or preparation ***in accordance with its use and exposure categories (identified uses). In addition specific uses may also be indicated***.
Where a chemical safety report is required, the safety data sheet shall contain information on all the identified uses relevant to the recipient of the safety data sheet. This information shall be consistent with the identified uses ***and exposure scenarios set out in the annex to the safety data sheet*** .	Where a chemical safety report is required ***for a substance or for particular components of a preparation***, the safety data sheet shall contain information on all the identified uses relevant to the recipient of the safety data sheet. This information shall be consistent with the identified uses ***set out in the chemical safety report***.

Justification

Amendment following on from the introduction of use and exposure categories. The indication in the safety data report of all relevant use and exposure categories is mandatory, whereas the additional indication of specific uses is optional. It is important to note that with a view to the consistency of the safety data sheet, further adjustments are required.

Amendment 293
Annex Ia, Point 3

3. The information given shall enable the recipient to identify readily the hazards of the components of the preparation. The hazards of the preparation itself shall be given under heading 3.	3. The information given shall enable the recipient to identify readily the hazards of the components of the preparation ***which are relevant to risk assessment and risk measures. Relevant components are those for which substance-specific measures have to be taken, irrespective of their use and exposure categories.*** The hazards of the preparation itself shall be given under heading 3.

Justification

In order for preparations to be used safely, it is not necessary for all components to be disclosed. Only those components for which specific measures have to be taken need to be indicated. Many safety measures, e.g. those for corrosive or inflammable preparations (such as the wearing of protective goggles, or fire protection measures) are not determined on a substance-specific basis.

Amendment 294
Annex Ia, Point 3.2.

3.2. For a preparation classified as dangerous according to Directive 1999/45/EC, the ***following*** substances shall be indicated, together with their concentration or concentration range::	3.2. For a preparation classified as dangerous according to Directive 1999/45/EC, the ***relevant*** substances shall be indicated, together with their concentration or concentration range:

Justification

In order for preparations to be used safely, it is not necessary for all components to be disclosed. Only those components for which specific measures have to be taken need to be indicated. Many safety measures, e.g. those for corrosive or inflammable preparations (such as the wearing of protective goggles, or fire protection measures) are not determined on a substance-specific basis.

Amendment 295
Annex Ia, Point 3.3.

3.3. For a preparation not classified as dangerous according to Directive 1999/45/EC, the ***following*** substances shall be indicated, together with their concentration or concentration range, if they are present in an individual concentration of ≥ 1% by weight for non-gaseous preparations and ≥ 0,2% by volume for gaseous preparations:	3.3. For a preparation not classified as dangerous according to Directive 1999/45/EC, the ***relevant*** substances shall be indicated, together with their concentration or concentration range, if they are present in an individual concentration of ≥ 1% by weight for non-gaseous preparations and ≥ 0,2% by volume for gaseous preparations:

Justification

In order for preparations to be used safely, it is not necessary for all components to be disclosed. Only those components for which specific measures have to be taken need to be indicated. Many safety measures, e.g. those for corrosive or inflammable preparations (such as the wearing of protective goggles, or fire protection measures) are not determined on a substance-specific basis.

Amendment 296
Annex Ia, Point 8.1.

Specify currently applicable specific control parameters including occupational exposure limit values and/or biological limit values. ***Values shall be given for the Member State where the substance or preparation is placed on the market. Give information on currently recommended monitoring procedures.***	Specify currently applicable specific control parameters including occupational exposure limit values and/or biological limit values.
Where a chemical safety report is required, the relevant DNELs and PNECs for the substance shall be given ***for the exposure scenarios set out in the annex to the safety data sheet.***	Where a chemical safety report is required, the DNELs and PNECs for the substance ***and for the relevant substances in a preparation*** shall be given ***for each use and exposure category.***
For preparations, it is useful to provide values for those constituent substances which are required to be listed in the safety data sheet according to heading 3.	***Product-related limit values for the protection of humans and the environment, particularly consumer protection, for substances in preparations and substances in articles shall also be indicated where relevant.***

Justification

Amendment following on from the introduction of use and exposure categories. For all relevant use and exposure categories, the safety data sheet must also indicate the appropriate

DNEL and PNEC values. If no DNEL or PNEC values have been derived, existing limit values should be given. It is important to note that, with a view to the consistency of the safety data sheet, further adjustments are required.

Amendment 297
Annex II, additional substances /groups

EINECS No	***Name/Group***	***CAS No***
	Noble gases	
	Substances commonly found in foodstuffs, such as citric acid, sugar, oils, fatty acids, etc.	
	Industrial gases such as hydrogen, methane, oxygen and biogas	
	Inorganic substances that are common, or the risks of which are well known, e.g. sodium chloride, soda, potash, calcium oxide, gold, silver, aluminium, magnesium, silicates, glass, frit	
265-995-8	***cellulose***	***65996-61-4***

Justification

The list of noble gases is incomplete; the same is true for the group of foodstuff ingredients and inorganic substances. With regard to industrial gases, a registration obligation seems disproportionate in the light of current knowledge. Cellulose: see Amendment to Article 3 (14) a (new). The Commission is called upon to complete these groups of substances within a year and to include further specific substances in the annex.

Amendment 298
Annex II, Table, EINECS No - Name/Group - CAS No (new rows)

231-959-9	***Oxygen O_2,***	***7782-44-7***
231-098-5	***Krypton Kr***	***7439-90-9***
231-110-9	***Neon Ne***	***7440-01-9***
231-168-5	***Helium He***	***7440-59-7***
231-172-7	***Xenon Xe***	***7440-63-3***
200-812-7	***Methane CH_4***	***78-82-8***

Justification

Noble gases cannot fall under Annex III, paragraph 8 as they are not considered dangerous within the meaning of Directive 67/548/EEC and because they are already regulated by the current regulations applicable to transport (ADR Regulations).

Methane should be included in Annex II because it is the main component of natural gas, which is already included in Annex III to the Regulation.

Amendment 299
Annex II, EINECS No - Name/Group - CAS No (new row)

265-995-8 Cellulose pulp 65996-61-4

Justification

Annex II already contains many naturally occurring substances including multi component ones.

Cellulose and starch are made up from the same monomeric saccharide, glucose. Glucose and starch are already included in Annex II. Therefore, cellulose pulp should also be added to the list of Annex II. Natural polysaccharide cellulose is the main component of higher plant cell walls and is the most abundant organic compounds on earth. Approximately 50 % of all biomass materials is cellulose. Cellulose is not classified as hazardous to human health or to the environment.

Amendment 300
Annex II, EINECS no - Name/Group - CAS no (new row)

231-096-4 Iron 7439-89-6

Justification

There is no evidence that iron presents risks to human health or the environment. Iron is a high tonnage material, thus it is likely to undergo considerable testing under REACH, with the consequent use of a large number of laboratory animals. The cost of testing and registration of iron would significantly outweigh any potential benefits.

Amendment 301
Annex III, paragraph 8

8. Minerals, ores, or substances occurring in nature if they are not chemically modified during their manufacturing, unless they meet the criteria for classification as dangerous according to Directive 67/548;	8. Minerals, ores, or substances occurring in nature ***and synthesised natural substances*** if they are not chemically modified during their manufacturing, unless they meet the criteria for classification as dangerous according to Directive 67/548;

Justification

Natural and synthesised natural substances should be treated the same, as it is impossible chemically and physically to distinguish between them. It makes no difference – particularly not for protecting health or the environment, whether for example sodium chloride (cooking salt) comes from natural sources or has been manufactured through a chemical process.

Amendment 302
Annex III, Point 8

8. Minerals, ores, or substances occurring in nature ***if they are not chemically modified during their manufacturing, unless they meet the criteria for classification as dangerous according to Directive 67/548***;	8. Minerals, ores, or substances occurring in nature; ***including botanically derived substances referred to in Article 3.***

Justification

Organic and inorganic substances should be treated equally in the registration process. Potential risk arising from minerals, ores or other natural substances can be addressed with other Community-legislation or at other stages of REACH.

Amendment 303
Annex III, Point 9

9. Natural gas, crude oil, coal.	9. Natural gas***, coke oven gas, blast furnace top gas, basic oxygen furnace gas***, crude oil, coal, ***coke***.

Justification

The process gases are produced and used within closed systems. Coke is a product which results from de-gasifying coal. In this process benzene, toluene, xylene , tar and other materials are extracted from coal and hence coke has fewer intrinsic hazardous properties. The specified gases are produced as by-products in coke ovens and integrated steel mills. They are used, like natural gas, oil and coal, to produce energy and heat.

Amendment 304
Annex III, Point 9

9. Natural gas, crude oil, coal.	9. Natural gas, ***coke oven gas, blast furnace***

	gas, basic oxygen furnace gas, crude oil, coal ***and coke.***

Justification

The process gases are produced and used within closed systems. All transport is by pipeline and the gases are never encountered by the general public.

Coke is a product arising from the degasification of coal. Thanks to the removal of other substances, coke holds fewer inherent risks and should therefore be exempted from the registration requirement.

The specified gases are used for energy and heat production, and should therefore – like natural energy sources – be exempted from the registration requirement.

Amendment 305
Annex III, Point 9

9. Natural gas, crude oil, coal.	9. Natural gas, ***liquefied petroleum gas (LPG),*** crude oil, coal.

Justification

LPG should be included in Annex III to the REACH Regulation in view of its natural origins, its similarities with other natural products listed in Annex III, and its known effects as regards safety, health and the environment.

Amendment 306
Annex III, Point 9

9. Natural gas, crude oil, coal.	9. Natural gas, crude oil, coal ***and coke;***

Justification

All naturally occurring substances even if covered by Directive 67/548 should be exempted as those substances do not constitute a priority, because their inclusion would drastically increase the number of substances subject to registration. They were also exempted from the EINECS reporting criteria.

Coke is a product which results from de-gasifying coal and therefore coke has fewer intrinsic hazardous properties and should therefore be exempted from registration.

Amendment 307
Annex III, Point 9 a (new)

9a) Impurities, unless they are imported or placed on the market themselves;

Justification

All naturally occurring substances even if covered by Directive 67/548 should be exempted as those substances do not constitute a priority, because their inclusion would drastically increase the number of substances subject to registration. They were also exempted from the EINECS reporting criteria.
Coke is a product which results from de-gasifying coal and therefore coke has fewer intrinsic hazardous properties and should therefore be exempted from registration.

Amendment 308
Annex III, Point 9 b (new)

9b) Homogeneous and heterogeneous alloys;

Justification

All naturally occurring substances even if covered by Directive 67/548 should be exempted as those substances do not constitute a priority, because their inclusion would drastically increase the number of substances subject to registration. They were also exempted from the EINECS reporting criteria.

Coke is a product which results from de-gasifying coal and therefore coke has fewer intrinsic hazardous properties and should therefore be exempted from registration.

Amendment 309
Annex III, Point 9 c (new)

9c) Intentional mixtures, produced by mixing or blending of ingredients. Components of such intentional mixtures should be reported separately. When however, chemical interaction between components happens that is incidental to the defined use and does not enhance the

technical nature of the product these should be regarded as by-products and not reported.

Justification

All naturally occurring substances even if covered by Directive 67/548 should be exempted as those substances do not constitute a priority, because their inclusion would drastically increase the number of substances subject to registration. They were also exempted from the EINECS reporting criteria.

Coke is a product which results from de-gasifying coal and therefore coke has fewer intrinsic hazardous properties and should therefore be exempted from registration.

Amendment 310
Annex III, Point 9 d (new)

9d) Inorganic catalysts

Justification

All naturally occurring substances even if covered by Directive 67/548 should be exempted as those substances do not constitute a priority, because their inclusion would drastically increase the number of substances subject to registration. They were also exempted from the EINECS reporting criteria.

Coke is a product which results from de-gasifying coal and therefore coke has fewer intrinsic hazardous properties and should therefore be exempted from registration.

Amendment 311
Annex III a (new)

List of potential PBT and vPvB substances

For the following phase-in substances, a registration shall be submitted 3 years after the entry into force:

[to be completed]

Justification

This Annex provides legal certainty as to which PBT and vPvB substances will have to be registered at an early stage. An Annex is necessary as otherwise registrants might be in

breach of the regulation because they missed the registration deadline. This could be the case if they find out at a later stage - after having generated information - that their substance is a PBT or vPvB substance. (amendment linked to amendment 20 on article 21, paragraph 1 (c).)

Amendment 312
Annex III b (new)

Further criteria for screening of substances between 1 and 10 tonnes and between 10 and 100 tonnes

Justification

Follows amendment on Article 43 aa 5 (new). This annex should be completed by the Commission later after proposals by the Agency.

Amendment 313
Annex IV, Guidance note

Annexes IV to IX specify the information that shall be submitted for registration and evaluation purposes according to Articles 9, ***11 and*** 12, ***39,*** 40 and 44. For ***the lowest tonnage level***, the standard requirements are in Annex V, and every time a new tonnage level is reached, the requirements of the corresponding Annex have to be added. For each registration the precise information requirements will differ, according to tonnage, use and exposure. The Annexes shall thus be considered as a whole, and in conjunction with the overall requirements of registration, evaluation and the duty of care.	Annexes IV to ***VI,*** IX specify the information that shall be submitted for registration and evaluation purposes according to Articles 9, 12, 40 and 44. For ***all substances over 1t/a***, the standard requirements are in Annex V***. When, on registering under Annex IXa, information is given on categories of exposure or use with repeated or long-term exposure of people and the environment, the additional information under VI must be given for each category. In principle information is not required below certain cut-off criteria for each category of exposure or use or content in preparations and products (e.g. the labelling thresholds for substances in preparations). Below these cut-off criteria, information is only required in particular cases where there is a reason (e.g. following an evaluation).***

Justification

The requirement to provide information according to threshold amounts and regardless of risk under Annex IV in conjunction with Annexes V-VIII will lead to many unnecessary experiments on animals and expensive data cemeteries. It is important to ensure that only data is collected that is really necessary for risk assessment.

Amendment 314
Annex IV, Step 1

The registrant should gather all existing available ***test data*** on the substance to be registered. Wherever practicable, registrations should be submitted by consortia, in accordance with Article 10 or 17. This will enable test data to be shared, thereby avoiding unnecessary testing and reducing costs. The registrant ***should*** also collect all other available information on the substance. This should include alternative data (e.g. from (Q)SARs, read-across from other substances, in-vitro testing, epidemiological data) which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests. ***In addition, information on exposure, use and risk management measures in accordance with Article 9 and Annex V should be collected.*** Considering all this information together, the registrant will be able to determine the need to generate further information. .	The registrant should gather all existing available ***information relevant to his risk assessment*** on the substance to be registered. Wherever practicable, registrations should be submitted by consortia, in accordance with Article 10 or 17. This will enable test data to be shared, thereby avoiding unnecessary testing and reducing costs. ***Therefore before determining the intrinsic data necessary for the risk assessment, the relevant information regarding the identified uses and existing and recommended risk management measures must be ascertained or determined.*** The registrant ***shall*** also collect all other available information on the substance ***concerning the identified uses, taking account of existing and recommended risk management measures.*** This should include alternative data (e.g. from (Q)SARs, read-across from other substances, in-vitro testing, epidemiological data) which may assist in identifying the presence or absence of hazardous properties of the substance and which can in certain cases replace the results of animal tests. Considering all this information together, the registrant will be able to determine the need to generate further information.

Justification

Clarification in the interest of SMEs. The wording about 'identified uses' follows on purely and simply from the indication of use and exposure categories. This is of particular importance to SMEs, since it serves to simplify the use of the system and preserve industrial and business secrets.

Amendment 315
Annex IV, Step 2

The registrant shall identify what information is required for the registration. ***First, the relevant Annex or Annexes to be followed shall be identified, according to tonnage. These Annexes set*** out the standard information requirements, ***but shall be considered in conjunction with Annex IX, which allows variation from the standard approach, where it can be justified. In particular,*** information on ***exposure, use and*** risk management measures ***shall be considered at this stage in order to*** determine the information needs for the substance.	The registrant shall identify what information is required for the registration. ***Annex V sets*** out the standard information requirements***. Annex IXa shows what additional information under Annex VI, for each category, is required. In principle data / information is not required below certain cut-off criteria for each category of exposure or use or content in preparations and articles (cf. Article 13 and for example the labelling thresholds for substances in preparations). I***nformation on ***identified uses and existing or recommended risk management measures shall*** determine the information needs for the substance.

Justification

Clarification in the interest of SMEs. The wording 'identified uses' includes by definition the information on use and exposure categories.

Amendment 316
Annex IV, Step 4

In some cases it will not be necessary to generate new data. However, where there is an information gap that needs to be filled, new data shall be generated (Annexes V ***and*** VI), ***or a testing strategy shall be proposed (Annexes VII and VIII), depending on the tonnage.*** New tests on vertebrates shall only be conducted or proposed as a last resort when all other data sources have been exhausted.	In some cases it will not be necessary to generate new data. However, where there is an information gap that needs to be filled, new data shall be generated (Annexes V***,***VI ***and IXa***). New tests on vertebrates shall only be conducted or proposed as a last resort when all other data sources have been exhausted.
In some cases, the rules set out in Annex V to IX may require certain tests to be undertaken earlier than or in addition to the standard requirements.	***Before carrying out tests on animals, the registrant must check whether the required information could be obtained from other sources, from valid alternatives to animal testing, such as QSAR, read-across from data on other substances, previous experience, epidemiological data, etc. He must also check whether the stated purposes of use would allow a measure to reduce exposure so that data collection, particularly from animal testing, would not be necessary. To this end he must first evaluate the existing risk management***

	measures with regard to each exposure category and check whether further risk management measures are possible. Before carrying out a test, the registrant must gather all other available information which might render these tests unnecessary. New tests on vertebrates shall only be conducted as a last resort, when all other data sources have been exhausted. If because of the exposure category under Annex IXa there is an obligation to provide information, this can be disregarded if it is technically impossible to obtain it or if from a scientific point of view it is unnecessary. In these cases the registrant must provide a plausible explanation in the registration.

Justification

The requirements concerning information and testing should therefore be tailored to the actual exposure situation and not according to quantities. Therefore firstly minimum data under Annex V are required. Further tests under Annex VI are only required, under legislation on protecting health, consumers and animals, if they are also really necessary under Annex IXa to evaluate safe use on the basis of actual exposure.

Amendment 317
Annex IV, Point 5

5. guidance on safe use concerning:	***deleted***
This information shall be consistent with that in the Safety Data Sheet, where such a Safety Data Sheet is required according to Article 29 of this Regulation.	
5.1. First-aid measures (safety data sheet heading 4)	
5.2. Fire-fighting measures (safety data sheet heading 5)	
5.3. Accidental release measures (safety data sheet heading 6)	
5.4. Handling and Storage (safety data sheet heading 7)	
5.5. Transport information (safety data sheet heading 14)	
Where a chemical safety report is not required, the following additional	

information is required:

5.6. Exposure Controls/Personal Protection (safety data sheet heading 8)

5.7. Stability and Reactivity (safety data sheet heading 10)

5.8. Disposal considerations

5.8.1. Disposal considerations (safety data sheet heading 13)

5.8.2. Disposal considerations (safety data sheet heading 13)

5.8.3. Information on recycling and methods of disposal for the public

Justification

The additional basic information on exposure helps companies to develop their safety data sheet or guidance on safe use and enables the Agency to screen dossiers submitted to identify priority substances in the tonnage range between 1 and 100 tonnes for which the information set out in Annex V or VI should be generated.

The old point 5 of Annex IV of the Commission proposal is moved to a new Annex Ic, as it contains information on risk management for substances which are not classified as dangerous, by following the structure of the safety data sheet of Annex Ic.

Amendment 318
Annex IV, Point 5 a (new)

5. Information on use and exposure categories

5.1. Use categories:

a) industrial use

b) professional use

c) consumer use

5.1.2. Specification of the use in each category:

a) use in closed system

b) use resulting in inclusion into or onto matrix

c) non-dispersive use

d) dispersive use

5.2. Exposure categories

5.2.1. Human exposure:

a) oral,

b) dermal

c) inhalative

5.2.2. Environmental exposure:

a) water

b) air

c) soil

5.3. Duration of exposure

a) accidental

b) occasional / short term

c) continuous / frequent

Justification

The additional basic information on exposure helps companies to develop their safety data sheet or guidance on safe use and enables the Agency to screen dossiers submitted to identify priority substances in the tonnage range between 1 and 100 tonnes for which the information set out in Annex V or VI should be generated.

The old point 5 of Annex IV of the Commission proposal is moved to a new Annex Ic, as it contains information on risk management for substances which are not classified as dangerous, by following the structure of the safety data sheet of Annex Ic.

Amendment 319
Annex V, Introduction, First Paragraph

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 1 tonne or more in accordance with Article 11 (1) ***(a)***.	Column 1 of this Annex establishes the standard information ***for substances manufactured or imported in quantities of 1 tonne or more per year.***
	The information set out in column 1 is required for all substances manufactured or imported in quantities of ***10 tonnes*** or more in accordance with Article ***11 (1) (b).***
	For substances in quantities of 1 to 10 tonnes, all available information on the properties of the substance is required to

be submitted in the registration dossier, which shall include as a minimum information on the physicochemical properties in accordance with Article 11 (1) (a).

Amendment 320
Annex V, Point 5.1., Column 2, , Specific rules for adaptation from Column 1 (new)

- Vapour Pressure

- Water solubility

- Partition coefficient n-octanol/water

- Flash point

- Flammability

- Explosive Properties

Amendment 321

Annex V, Point 5.2., Column 2, Explanation (new row)

- Boiling Point

- Relative Density

- Surface Tension

- Self-ignition temperature

Oxidising Properties

Or. en

Amendment 322
Annex V, point 5.6 and point 5.14

Deleted

Justification

Both points are deleted, including their descriptive parts, since testing surface tension is generally meaningless for evaluation and risk reduction measures. A general test of granulometry seems disproportionate.

Amendment 323
Annex V, Point 6.5 (new), left column

	6.5. Acute toxicity
	The study shall be conducted for one route, preferably oral, unless the registrant considers another route more appropriate.
	For gases and volatile liquids (vapour pressure above 10-2 Pa at 20°C) the information shall be provided for the inhalation route (6.5.2).
	For substances other than gases in quantities of 100 tonnes or more per year per manufacturer or importer, the information mentioned under 6.5.1. to 6.5.3. shall be provided for at least two routes, one of which the oral route. The choice for the second route will depend on the nature of the substance and the likely route of human exposure. If there is only one route of exposure, information for only that route need be provided.
	6.5.1. By oral route
	6.5.2. By inhalation
	6.5.3. By dermal route

Justification

The Commission proposal requires information on acute toxicity only for substances in quantities of 10 tonnes or more per year. Information on acute toxicity for one exposure route, however, should also be required for selected priority substances in the tonnage range of 1 to 10 tonnes, which will be identified in the screening that the Agency will perform as set out in Articles 43 aa. For non-priority substances only information that is already available is required to be submitted. Thereby, this more flexible system achieves overall a better balance between information needs and cost efficiency than the Commission proposal. (amendment linked to compromise amendment 2 on Art. 5(2))

Amendment 324
Annex V, Point 6.5 (new), right column

	6.5. The study/ies do(es) not need to be conducted if:
	precise doses of the substance cannot be administered due to the chemical or

physical properties of the substance; or

the substance is corrosive; or

the substance is flammable in air at room temperature.

The appropriate second route shall be chosen on the following basis:

6.5.2. Testing by the inhalation route is appropriate if:

1) exposure of humans via inhalation is likely; and

2) one of the following conditions is met: the substance has a vapour pressure above 10-2 Pa at 20 °C; or

one of the following conditions is met: the substance has a vapour pressure above 10-2 Pa at 20 °C; or

the substance will be used in a manner which generates aerosols, particles or droplets in an inhalable size range (> 1% on a w/w basis of particles with MMAD < 100 µm).

6.5.3. Testing by the dermal route is appropriate if:

1) skin contact in production and/or use is likely; and

2) the physicochemical properties suggest a significant rate of absorption through the skin; and

3) one of the following conditions is met:

- toxicity is observed in an acute oral toxicity test at low doses; or

- systemic effects or other evidence of absorption is observed in skin and/or eye irritation studies; or

- in vitro tests indicate significant dermal absorption; or

- significant acute dermal toxicity or dermal penetration is recognised for structurally-related substances.

Testing by the dermal route is inappropriate if the absorption by the skin is unlikely as indicated by molecular weight (MW > 800 or molecular diameter > 15 Å) and low liposolubility (log Kow below -1 or above 4).

Justification

The Commission proposal requires information on acute toxicity only for substances in quantities of 10 tonnes or more per year. Information on acute toxicity for one exposure route, however, should also be required for selected priority substances in the tonnage range of 1 to 10 tonnes, which will be identified in the screening that the Agency will perform as set out in Articles 43 aa. For non-priority substances only information that is already available is required to be submitted. Thereby, this more flexible system achieves overall a better balance between information needs and cost efficiency than the Commission proposal. (amendment linked to compromise amendment 2 on Art. 5(2))

Amendment 325
Annex V, Point 7.1.1., left column

7.1.1. Short term toxicity testing on Daphnia	7.1.1. Short term toxicity testing on Daphnia ***or fish***

Justification

Undertakings should be free to submit existing short-term toxicity tests on fish instead of toxicity on daphnia

Amendment 326
Annex V, Point 7.2. (new), left column

	7.2. Degradation
	7.2.1. Biotic
	7.2.1.1. Ready biodegradability

Justification

The Commission proposal requires information on biodegradation only for substances in quantities of 10 tonnes or more per year. Such information should also be required for selected priority substances in the tonnage range of 1 to 10 tonnes, which will be identified in the screening that the Agency will perform as set out in Articles 43 aa. For non-priority substances only information that is already available is required to be submitted. (amendment linked to compromise amendment 2)

Amendment 327
Annex V, Point 7.2. (new), right column

	7.2. The simulation studies (Annex VII, 7.2.1.2 to 7.2.1.4.) shall be proposed by the registrant 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.
	7.2.1.1. The study does not need to be conducted if the substance is inorganic.

Justification

The Commission proposal requires information on biodegradation only for substances in quantities of 10 tonnes or more per year. Such information should also be required for selected priority substances in the tonnage range of 1 to 10 tonnes, which will be identified in the screening that the Agency will perform as set out in Articles 43 aa. For non-priority substances only information that is already available is required to be submitted. (amendment linked to compromise amendment 2)

Amendment 328
Annex VI, Introduction, First Paragraph

Column 1 of this Annex establishes the standard information required for all substances manufactured or imported in quantities of 10 tonnes or more in accordance with Article 11 (1) (***b***).	Column 1 of this Annex establishes the standard information ***for substances manufactured or imported in quantities of 10 tonnes or more per year.***
	The information set out in column 1 are required for all substances manufactured or imported in quantities of ***100 tonnes*** or more in accordance with Article ***11 (1) (c).***
	For substances in quantities of 10 to 100 tonnes, the information set out in Annex V and all further available information on the properties of the substance is required to be submitted in the registration dossier in accordance with Article 11 (1) (b).

Justification

Amendment 329
Annex IX, Point 1.5., Point 3

(3) a constant pattern in the changing of the potency of the properties across the category.	(3) a constant pattern in the changing of the potency of the properties across the category ***and common mechanism of action***.

Justification

It seeks to substantiate the Grouping of substances and read-across approach allowing registration per group of substances and thereby significantly decreasing the number of dossiers submitted for registration. The amendment introduces a fourth criteria allowing for the grouping of substances with the same toxicity profiles. The amendment also provides for the obligation for the Commission to issue a detailed methodology.

Amendment 330
Annex IX, Point 1.5., Subparagraph 3 a (new)

	The endpoints for classification and labelling and for Risk Assessment of substances that are complex and of variable composition may be determined from data on their significant constituents using their highest concentrations in the substance. The agency, after consulting the stakeholders concerned and other interested parties, shall issue a detailed and scientifically justified methodology for the grouping of substances within 2 years from the adoption of the legislation.

Justification

It seeks to substantiate the Grouping of substances and read-across approach allowing registration per group of substances and thereby significantly decreasing the number of dossiers submitted for registration. The amendment introduces a fourth criteria allowing for the grouping of substances with the same toxicity profiles. The amendment also provides for the obligation for the Commission to issue a detailed methodology.

Amendment 331
Annex XI, Introduction, First Paragraph

The purpose of this Annex is to set out how downstream users are to assess and document that the risks arising from the substance(s) they use are adequately controlled during their use for a use not covered by the safety data sheet supplied to them and that other users further down the supply chain can adequately control the risks. The assessment shall cover the life-cycle of the substance, from its receipt by the downstream user, for his own uses and for his identified uses further down the supply chain. The assessment shall consider the use of the substance on its own, in a preparation or in an article.	The purpose of this Annex is to set out how downstream users are to assess and document that the risks arising from the substance(s) they use are adequately controlled during their use for a use not covered by the safety data sheet supplied to them and that other users further down the supply chain can adequately control the risks. The assessment shall cover the life-cycle of the substance, from its receipt by the downstream user, for his own uses and for his identified uses ***in quantities of 1 tonne or more per year*** further down the supply chain. The assessment shall consider the use of the substance on its own, in a preparation or in an article.

Justification

Improves workability by limiting uses that have to be considered in the chemical safety report to those in one tonne and more. According to the Commission proposal a use would have to be dealt with even in very small quantities.

Amendment 332
Annex IX, Point 3, First Paragraph

Testing in accordance with Annexes ***VII and*** VIII may be omitted, based on ***the*** exposure scenario(s) developed in the Chemical Safety Report.	Testing in accordance with Annexes ***VI to*** VIII may be omitted, based on exposure scenario(s) developed in the Chemical Safety Report.

Justification

The aim of REACH is not to generate scientific information on all substances – regardless of actual risk – but to focus on information that is needed to adequately control the risks from the use of substances.

Therefore also for substances between 10 and 100 tonnes, the generation of information shall not be required, if the exposure of humans or the environment is insignificant.

Amendment 333
Annex IX, Point 3, Paragraph 2 a (new)

Testing in accordance with Annex V may be omitted, if exposure is insignificant and adequate justification and documentation is provided.

Justification

Also for substances below 10 tonnes selected as priority substances by the Agency's screening, the generation of information shall not be required, if the exposure of humans or the environment is insignificant.

Amendment 334
Annex IX, Point 3

Testing in accordance with Annexes ***VII and*** VIII may be omitted, based on ***the*** exposure scenario(s) developed in the Chemical Safety Report.	Testing in accordance with Annexes ***VI to*** VIII may be omitted, based on exposure scenario(s) ***or use and exposure categories*** developed in the Chemical Safety Report.

Justification

The aim of REACH is not to generate scientific information on all substances – regardless of actual risk – but to focus on information that is needed to adequately control the risks from the use of substances.

Therefore also for substances between 10 and 100 tonnes, the generation of information shall not be required, if the exposure of humans or the environment is insignificant.

Also for substances below 10 tonnes selected as priority substances by the Agency's screening, the generation of information shall not be required, if the exposure of humans or the environment is insignificant. (amendment linked to compromise amendment 2)

Amendment 335
Annex IX, Point 3.1., 3.2. and 3.3. (new)

3.1. Testing in accordance with Annexes VI to VIII may be omitted, based on the

exposure scenario(s) or use and exposure categories developed in the Chemical Safety Report.

3.2. The omission of information shall be considered acceptable if:

i) at a place of work, the ambient air concentration does not exceed 50 µg/m³.

ii) the manufacturing and identified use(s) of a substance take place only in self contained facilities.

iii) the substance is used in the industrial or commercial sector in a preparation of a maximum mass concentration of 0.1 %.

iv) the substance is used by private consumers in concentrations not exceeding 0.1 %.

v) the substance is used in the manufacturing of consumer products and:

a) the substance disappears completely during the product's manufacturing; or

b) the substance is permanently integrated into a compound in the product or otherwise completely contained in the product.

3.3 In all other cases, adequate justification and documentation shall be provided, including the following:

i) the types of environmental compartments;

ii) the human populations exposed;

iii) risk management measures;

iv) routes of exposure

v) duration and frequency of exposure

vi) protection of animal lives.

Justification

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 Persistant Organic Pollutants}
References	COM(2003)0644 – C5-0531/2003 – 2003/0256(COD)
Committee responsible	ENVI
Committee asked for its opinion Date announced in plenary	IMCO 16.9.2004
Enhanced cooperation	Yes
Draftsman Date appointed	Hartmut NASSAUER 28.7.2004
Discussed in committee	24.11.2004 19.1.2005 19.4.2005 24.5.2005 14.6.2005 4.7.2005 12.7.2005 5.9.2005 13.9.2005
Date amendments adopted	13.9.2005
Result of final vote	for: 33 against: 3 abstentions: 0
Members present for the final vote	Mia De Vits, Bert Doorn, Janelly Fourtou, Małgorzata Handzlik, Malcolm Harbour, Christopher Heaton-Harris, Anna Hedh, Edit Herczog, Anneli Jäätteenmäki, Henrik Dam Kristensen, Alexander Lambsdorff, Kurt Lechner, Arlene McCarthy, Manuel Medina Ortega, Bill Newton Dunn, Béatrice Patrie, Zita Pleštinská, Guido Podestà, Zuzana Roithová, Luisa Fernanda Rudi Ubeda, Heide Rühle, Leopold Józef Rutowicz, Andreas Schwab, Eva-Britt Svensson, József Szájer, Jacques Toubon, Bernadette Vergnaud, Barbara Weiler, Phillip Whitehead, Joachim Wuermeling
Substitutes present for the final vote	Charlotte Cederschiöld, Gisela Kallenbach, Cecilia Malmström, Maria Matsouka, Joseph Muscat, Hartmut Nassauer
Substitutes under Rule 178(2) present for the final vote	Lena Ek, Dieter-Lebrecht Koch