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Committee on International Trade

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OPINION

of the Committee on International Trade

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 Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} (COM(2003)0644– C5-0530/2003 – 2003/0256(COD))

Draftsperson: Godelieve Quisthoudt-Rowohl

PA_Leg

SHORT JUSTIFICATION

Introduction

The European chemicals industry accounts for over €100 billion of EU exports while REACH will also affect the many firms that use imported chemicals as inputs. As a result, the Trade Committee's interest in this proposal is clear: REACH will have a substantial impact on trade flows and raise issues of WTO compatibility.

Impact of Commission proposal on EU trade in chemicals

The EU has run a substantial trade surplus in the chemicals sector for many years. Although there is a tendency to think of large multinationals when speaking of "the chemicals industry", it should be recognised that there are also many small and medium producers and distributors. Almost 1/3 of chemical industry patents are held by SMEs.

The proposed amendments seek to address four broad concerns:

a) the withdrawal from the EU market of substances and preparations whose registration and other costs exceed their profit margins. This is likely to be of particular concern for smaller firms who will also struggle to find the required human resources. A stronger role for the Agency should be of particular assistance for smaller importers;

b) the requirements on importers of preparations would be very difficult if not impossible to fulfil (as tens or hundreds of component substances could need to be registered, some of which might be commercially confidential to firms other than the importer);

c) loss of competitiveness in 3rd markets when competing with firms producing in countries with lower regulatory costs. Additional costs will be particularly damaging to producers of standard products where competition is primarily on cost;

d) reduced innovation affecting longer-term competitiveness, with resources being diverted from research to testing. These last two points will encourage relocation of production to friendlier regulatory climates.

Impact of Commission proposal on EU trade in other products

Competitiveness: REACH's impact would go well beyond the chemicals industry, affecting all firms using chemicals as inputs. Imported articles could contain non-registered substances (provided they are not released) whereas EU produced articles could not, creating an incentive for production outside the EU.

The position of the metals industry is of particular concern as it relies on high volume imports of (typically) low risk raw materials. Additional costs could discourage recycling or redirect such materials to other markets. The coverage of REACH should therefore be substantially reduced by excluding materials such as metals, alloys, minerals and scrap.

A risk based approach

The proposed amendments seek to move from a quantity based to a risk based approach so as to reduce the likelihood of WTO challenges. Under such an approach each product will have a clear, transparent risk sheet which clearly outlines the chemicals' exposure and hazard data.

The need for a strong agency

The proposed amendments give the newly created European Chemicals Agency additional responsibilities for the assessment and evaluation of substances, as well as for the determination of the risk category for each substance.

Seeking international consensus on a common approach to REACH

The risk of an extended period of uncertainty caused by WTO proceedings, possibly followed by the need for early revision of the Regulation could be greatly reduced by seeking an international consensus, at least with the EU's main trading partners, such as the United States, Japan and Korea, involving a mutual recognition of testing procedures and uniform information requirements. A common approach would cut the costs since test information could be shared, and assist firms operating in several markets. Initiatives such as the OECD Screening Information Data Set, the Rotterdam Agreement on the transport of dangerous chemicals and pesticides, as well as the US High Production Volume Chemicals Challenge Programme already provide a basis for such negotiations.

AMENDMENTS

The Committee on International Trade calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
	Amendment 1 Recital 4 a (new)
	(4a) REACH should be so designed and applied as to avoid weakening the competitiveness of European trade and industry or damaging trade with third countries. In the light of this, prioritisation

[1] OJ C ... /Not yet published in OJ.

of risks is of the first importance, as is the premise that regulation must not impose any requirements on our trading partners other than that they should be compatible with the free-trade principles in force under WTO provisions.

Justification

In our globalised world, it is important that REACH should not impair the competitiveness of European trade and industry. Nor must REACH disturb relations with our trading partners.

Amendment 2
Recital 15 a (new)

(15a) In order to ensure consistent application of the new system, the Agency should be given a predominant role in the registration, evaluation and authorisation process.

Justification

A consistent approach is of particular importance for smaller international traders who cannot be expected to handle a variety of national practices.

Amendment 3
Recital 15 b (new)

(15b) To further limit costs and facilitate international trade, the Agency shall take the greatest possible account of existing and emerging international standards in the regulation of chemicals, with a view to promoting the broadest possible international consensus.

Justification

Amendment 4
Recital 24

(24) Requirements for generation of information on substances should be tiered according to the volume of manufacture or importation of a substance, because these	(24) Requirements for generation of information on substances should be tiered according to the volume of manufacture or importation of a substance, because these

provide an indication of the potential for exposure of man and the environment to the substances, and should be described in detail.	provide an indication of the potential for exposure of man and the environment to the substances, and should be described in detail. ***If there are risk assessments based on practical use of the substance in question, these should be taken into account. The aim should be to ensure that the amount of information required is geared to experience of practical use.***

Justification

It is important to take account of the experience which has already been gained during the hundreds of years for which some chemicals have been used.

Amendment 5
Recital 28 a (new)

	(28a) For reasons of workability, waste and materials used as secondary raw material or as a source of energy should be exempted. Generating value ('valorisation') from waste and materials used as secondary raw material, or as a source of energy in recovery operations, contributes to the EU objective of sustainable development, and this Regulation should not introduce requirements which reduce the incentives for such recycling and recovery.

Justification

Including recycled raw materials in the scope of REACH could seriously hamper recycling and recovery and thereby increase the need for non-renewable resources. It should be made clear that a) double legislation is to be avoided, b) recycling is in no way discouraged by REACH. Recycling efforts, operating permits and the used of recycled materials as 'secondary raw materials extracted from waste' are already regulated under existing Community legislation.

Amendment 6
Recital 28 b new

	(28b) Ninety per cent of metals are used in the form of metallic alloys whose characteristics are such that it may not be

possible accurately to determine their properties using currently available conventional methods. It is therefore necessary to develop a specific method of classification which takes into account their particular chemical properties.

Justification

Alloys' hazard characteristics differ from those of their constituent metals. The present EU classification rules for "preparations" (Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations) provides no adequate guidance on how to assess properties of alloys. However it contains a recital (n° 10) indicating the need to develop such a specific approach for alloys.

Amendment 7
Recital 29 a (new)

(29a) In order to help companies, and in particular small and medium-sized enterprises, comply with requirements of this Regulation, the Member States, in cooperation with the Commission, should put in place a support network.

Justification

Many of the companies that will be affected by REACH are small and medium-sized enterprises (SMEs). Special care should be taken to prevent the legislation from putting too high an administrative burden on them. The best practical solution could however vary from one Member State to another, depending on the specific institutional framework in place. Member States should therefore be responsible for putting in place an adequate network of necessary support measures.

Amendment 8
Recital 82 a (new)

(82a) In order to reduce its costs and improve its international acceptability, the European approach should be as closely aligned as possible with international initiatives including the UNEP "Strategic Approach to International Chemicals Management", the Organization for

Economic Cooperation and Development's "Council Act on High Production Volume (HPV) Chemicals", the International Council of Chemical Associations HPV Initiative and the U.S. Environmental Protection Agency's HPV Challenge.

Justification

In order to avoid unnecessary costs, maximum possible use should be made of existing information and that being developed through international cooperation. In addition, greater use of international standards will reduce the risk of the Regulation being found to be incompatible with WTO agreements.

Amendment 9
Recital 104 c (new)

(104c) The Commission should make efforts to guarantee that the growing openness of EU markets to world-wide imports is accompanied by the introduction of more demanding requirements in relation to the 'fairness' of trade (inclusively in the WTO context); as soon as possible, REACH requirements must be included.

Justification

It is essential that the opening to international trade be accompanied by the creation of a level playing field that includes environmental and public health requirements. Given its relevance, REACH is a major element in this process.

Amendment 10
Recital 104 d (new)

(104d) Any manufacturer, importer or downstream user manufacturing, using or importing a substance, a preparation or an article containing such a substance or preparation, who knows or could reasonably have foreseen that these operations could adversely affect human health or the environment, should take the necessary measures to prevent, limit or remedy such effects.

Justification

Irrespective of production volume there needs to be a clarification that industry should be responsible for taking measures to ensure the safety of chemicals.

Amendment 11
Recital 104 e (new)

(104e) Any manufacturer, importer or downstream user that provides a substance or preparation to a downstream user should ensure adequate communication and information exchange to prevent, limit or remedy adverse effects on human health or the environment.

Justification

Irrespective of production volume there needs to be a clarification that industry should be responsible for taking measures to ensure the safety of chemicals.

Amendment 12
Article 1, paragraph 2

2. The purpose of this Regulation is to ensure the free circulation of such substances on the internal market.	***2.*** The purpose of this Regulation is to ensure the free circulation of chemical substances on the internal market ***with due regard for the obligations entered into by the EU and its Member States in the framework of international trade agreements, in particular within the WTO***.

Amendment 13
Article 2, paragraph 1, subparagraph (c) a (new)

(ca) special uses of registered substances which are intended solely for export to third countries;

Justification

This is intended to create a level playing field for competition outside the European internal market and to ensure compliance with WTO rules.

Amendment 14
Article 2, paragraph 1, subparagraph c a (new)

(ca) recycling and recovery operations;.

Justification

Including waste or secondary raw materials or materials for energy recovery extracted from waste in the scope of REACH would impose disproportionate requirements on recycling or recovery without bringing any additional benefit for human health or the environment and create a disincentive for the growing waste recycling and recovery practices in the EU.

Amendment 15
Article 2, paragraph 1, point (c b) (new)

(cb) substances in medicinal products for human or veterinary use within the meaning of Council Regulation (EEC) No 2309/93[1], Directive 2001/82/EC of the European Parliament and of the Council[2] and Directive 2001/83/EC of the European Parliament and of the Council[3];

1 OJ L 214, 24.8.1993, p. 1.

2 OJ L 311, 28.11.2001, p. 1.

3 OJ. L 311, 28.11.2001, p. 67.

Justification

Duplicate legal provisions should be avoided.

Amendment 16
Article 2, paragraph 1, point (c c) (new)

(cc) substances in food within the meaning of Regulation 178/2002/EC[1], including food additives within the meaning of Council Directive 89/107/EEC[2] and flavourings according to the definitions pursuant to Regulation 2232/96/EC[3] and pursuant to Commission Decision 2000/489/EC[4];

1 OJ L 31, 1.2.2002, p. 1. Regulation amended by Regulation (EC) No. 1642/2003 (OJ L 245, 29.9.2003, p. 4).

2 OJ L 40, 11.2.1989, p. 27.

3 OJ L 299, 23.11.1996, p.1

4 OJ L 197, 3.8.2001, p.3

Amendment 17
Article 2, paragraph 1, point (c d) (new)

(cd) substances in animal feed, including feed additives within the scope of Regulation (EC) No 1831/2003 on additives for use in animal nutrition[1], and animal feed within the scope of Directive 84/471/EEC[2];

1 OJ L 192, 29.5.2004, p.34

2 OJ L 266, 6.10.1984, p.18

Amendment 18
Article 2, paragraph 1, point (c e) (new)

(ce) substances in medical devices within the scope of Directives 90/385/EEC[1], 93/42/EEC[2] and 98/79/EC[3];

1 OJ L 189, 20.7.1990, p. 17.

2 OJ L 169, 12.7.1993, p. 1.

3 OJ L 331, 7.12.1998, p. 1.

Amendment 19
Article 2, paragraph 1, point (c f) (new)

(cf) substances in materials which come into contact with foodstuffs within the meaning of Council Directive 89/109/EEC[1];

1 OJ L 40, 11.2.1989, p. 38.

Amendment 20
Article 2, paragraph 1, point (c g) (new)

(cg) substances in plant protection products within the meaning of Council Directive 91/414/EEC[1];

1 OJ L 230, 19.8.1991, p. 1.

Amendment 21
Article 2, paragraph 1, point (c h) (new)

(ch) substances in biocidal products within the meaning of Directive 98/8/EC of the European Parliament and of the Council[1];

1 OJ L 123, 24.4.1998, p. 1.

Amendment 22
Article 2 paragraph 1, point (c i) (new)

(ci) substances in cosmetic products within the scope of Council Directive 76/768/EEC[1];

1 OJ L262, 27.9.1976, p. 169.

Amendment 23
Article 2, Paragraph 1 (c j) (new)

(cj) naturally occurring raw materials not marketed to the public and solely for use in installations regulated under Council Directive 96/61/EC[1];

1 OJ L 257, 10/10/1996 P. 0026

Justification

Many primary raw materials are very complex and highly variable in composition leading to the need for multiple Registrations and Authorisations. Excluding raw materials from Registration only (under chapter 3) would therefore be insufficient.

Metal production plants are regulated under the IPPC and other relevant EU worker protection and environmental legislation. Potential workplace and environmental concerns associated with the use of primary natural raw materials are therefore adequately covered.

Amendment 24
Article 2, paragraph 1, subparagraph (cb) (new)

(cb) Substances used in response to unforeseen problems that would result in quality deteriorations or a halt to production, under all of the following conditions:

(i) prior registration is not possible because of urgency, and

(ii) a subsequent registration takes place if a repetition of the substance use is likely, and

(iii) the unforeseen use respects existing legislation on workers' safety.

Justification

Unforeseen problems with process chemicals may require immediate reactions so as to avoid suboptimal production or even a halt to it ('trouble-shooting'). The concept of prior registration for substance uses can only be respected under the assumption that all possible problems and the required responses are foreseeable. This is not the case. An exemption for 'trouble-shooting' is therefore required, which, however, should be kept within strict boundaries so as not to become a loophole in the REACH system. The three cumulative conditions set should ensure this.

Amendment 25
Article 2 a (new), title

Article 2a

Restricted use

Amendment 26

Article 2 a (new), introductory part

The provisions of this Regulation shall apply to the following categories of substances with the restrictions here specified:

Amendment 27
Article 2 a (new), paragraph 1

1. Natural and nature-identical substances shall be registered only where the Agency has classified them, in principle, as dangerous in regard to their use and exposure thereto and where those substances are not already governed by other rules.

Amendment 28
Article 2 a (new), paragraph 2

2. As long as substances are used exclusively in the context of scientific research and development activities, in closed systems or as intermediates, without consumers or the environment being directly exposed thereto, their use shall not require compliance with the obligations laid down in this Regulation.

Amendment 29
Article 2 a (new), paragraph 3

3. Metallic alloys as special forms of preparations shall be assessed separately by the Agency on the basis of their particular specific properties and shall be classified according to their individual registration requirements.

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 fermentation. The compositions of such substances vary depending on the genus, species, growing conditions of their 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 for under Annex III (to be amended accordingly) for natural substances and ensure legal certainty in the implementation of REACH provisions.

Amendment 31
Article 3 paragraph 4 a (new)

4a. 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 32
Article 3, Paragraph 4 b (new)

4b. Naturally occurring raw materials include crude oil, gas and coal, minerals, ores, concentrates substances occurring in nature and materials derived from them by mineralogical processes or physical transformation processes;

Justification

Definition is required for new sub paragraph Article 2 paragraph 1 (c j)

Amendment 33
Article 3, paragraph 12 a (new)

12a. Categories of use means the classification pursuant to Annex Ic 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 will form a necessary basis for risk assessment by the Agency.

Amendment 34
Article 3, paragraph 12 b (new)

12b. Exposure categories means 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 will form a necessary basis for risk assessment by the Agency.

Amendment 35
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, thereby forming a necessary basis for risk assessment by the Agency.

Amendment 36
Article 3, paragraph 14

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***/preparation*** (hereinafter called *synthesis*):

Justification

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

Amendment 37
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 38
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 a preparation 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

It should be made clear that a product development process can involve all aspects of a production process, and that companies are allowed to test prototypes of articles as part of a Ppord process.

Amendment 39
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 ***including research by trial and error involving downstream users***;

Justification

1 tonne is too restrictive. Research by trial and error between a chemical producer and his customer (downstream user) are a major source of innovation in terms of new usages, functions and applications. This should be part of the definition in order to preserve innovation.

Amendment 40
Article 3, paragraph 26

26. ***Undesirable*** use means a use by downstream users which the registrant advises against;	26. ***Unsupported*** use means a use by downstream users which the registrant advises against ***for safety reasons***;

Justification

The words 'undesirable use' have an emotional rather than scientific or legal connotation, which is unsuitable in legislation. The registrant should have the right to advise against uses they consider unsafe but not against uses they do not wish to register, for example for economic reasons.

Amendment 41
Article 3, paragraph 28

28. Per year means per calendar year unless stated otherwise;	28. Per year means per calendar year***. Except in the case of new substances, quantities per year shall be calculated on the basis of the average of the preceding three calendar years*** unless stated otherwise;

Justification

This allows flexibility in the REACH system by taking fluctuations in production volumes into

account. Furthermore, it eliminates the risk that a company would suddenly have to comply with higher or lower data requirements due to such fluctuations in demand. For substances not produced before, only the current year should be taken into account.

Amendment 42
Article 3, paragraph 29 a (new)

29a. Use and exposure categories (UEC) summarise exposure scenarios that are characterised by comparable use as referred to in Article 3 (12) and (25). They describe all conditions that determine exposure. The constituent elements of UEC are independent of the sector:

- Basic fields of application

- industrial use

- professional use

- consumer use

- Routes of exposure

- Main routes of intake by humans

(oral, by inhalation, dermal)

- Paths of release into the environment

(air, water, soil, biota)

- Duration of exposure

- single/short-term

- occasional

- permanent/long-term

These use and exposure categories will result in comparable recommended risk management measures.

Justification

Use and exposure categories (UEC) are intended significantly to facilitate the processes induced by REACH, such as the registration process as well as communication and the chemical safety assessment along the supply chain, without affecting the objectives of REACH.

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;

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 b (new)

29b. Risk categories means categories of potential risks to be established by the Agency on the basis of the pre-registration data, in particular the data concerning category of use, exposure category, and exposure scenario.

Justification

A risk-based approach must be consistently taken in order to achieve WTO compatibility for REACH. The Agency should be responsible for this.

Amendment 45
Article 3, paragraph 29 c (new)

29c. 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 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 and Directive 2001/83/EC of the European Parliament and of the Council;

(b) as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC;

(c) as a flavouring in foodstuffs within the scope of Commission Decision 1999/217/EC;

(d) as an additive in feedingstuffs within the scope of Council Directive 70/524/EEC;

(e) in animal nutrition within the scope of Council Directive 82/471/EEC.

Justification

All the derogations have been transferred to Article 2, in the interests of clarity.

Amendment 47
Article 4, paragraph 2, point (c a) (new)

(ca) substances which are manufactured, imported and used for scientific research and development or for product- and process-oriented research and development.

Justification

In the interests of strengthening innovative capacity, substances which are used for R&D activities should basically be exempted from the registration requirement so that research and testing activities are not relocated to non-EU countries. Such substances are used by trained specialist staff under controlled conditions.

Amendment 48
Article 6, paragraph 1

1. ***Any producer or importer*** of articles shall ***submit a registration to the Agency for*** any substance ***contained*** in those articles***,*** if ***all*** the following conditions ***are*** met:	1. ***The Agency may decide that producers or importers*** of articles shall ***register*** any substance in those articles ***in accordance with this Title*** if ***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 and if one of the following conditions ***is*** met:
(a) ***the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year, each article type being considered separately;***	(a) ***the criteria referred to in Article 54(a) to (e) are fulfilled or***
(b) ***the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC;***	(b) ***there is a correspondence with Article 54(f) or***
(c) ***the substance is intended to be released under normal and reasonably foreseeable conditions of use.***	(c) ***the Agency classifies the substance as requiring registration on the basis of the pre-registration data.***

Amendment 49
Article 6, paragraph 2

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.	

Justification

A risk-based approach must be consistently taken in order to achieve WTO compatibility for REACH.

Amendment 50
Article 6, paragraph 3

If the conditions in paragraph 2 are met, the information to be notified shall include the following, in the format specified by the Agency in accordance with Article 108:	***deleted***
(a) the identity and contact details of the producer or importer;	
(b) the registration number(s) referred to in Article 18 (1), if available;	
(c) the identity of the substance(s) as specified in section 2 of Annex IV;	
(d) the classification of the substance;	
(e) a brief description of the use(s) of the article;	
(f) the tonnage range of the substance, such as 1-10 tonnes, 10-100 tonnes and so on.	

Justification

Linked to the amendment to Article 6(2) by the same author. As the use of hazardous substances in articles should be subject to the registration requirements as given in the amendment to Article 6(1), there is no more need for a notification.

Amendment 51
Article 6, paragraph 4

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

Justification

Linked to the amendments to Article 6(2) by the same author. As the use of hazardous substances in articles should be subject to the registration requirements as given in the amendment to Article 6(1), there is no more need for this provision.

Amendment 52
Article 6, paragraph 5

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***, category of use or exposure category*** by ***another*** actor.

Amendment 53
Article 6, paragraph 6

6. ***Paragraphs*** 1 ***to 4*** shall apply 3 months after the deadline specified in Article ***21(3)***.	6. ***Paragraph*** 1 shall apply 3 months after the deadline specified in Article ***21(2)***.

Amendment 54
Article 6, paragraph 7

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 ***paragraph 1*** shall be adopted in accordance with the procedure referred to in Article 130(3).

Amendment 55
Article 6 b (new)

	Article 6b
	European quality mark
	By …. * the Commission shall present to the European Parliament and the Council a report and, if appropriate, a legislative proposal on the creation of a European quality mark designed to identify and promote articles which, at each stage of the production process, have been produced in compliance with the requirements stemming from this Regulation.
	**** Two years after the entry into force of this Regulation.***

Justification

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

Regulation.

Amendment 56
Article 7, paragraph 2

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:	***2. If the substances intended or employed for research and development are considered particularly dangerous or toxic, the manufacturer or importer shall notify them and provide the Agency with the data sheet required.***
(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.	

Amendment 57
Article 7, paragraph 3

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.	***deleted***

Amendment 58
Article 7, paragraph 4

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.	***deleted***

Amendment 59
Article 7, paragraph 5

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..	***deleted***

Amendment 60
Article 7, paragraph 6

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

Amendment 61
Article 7, paragraph 7

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	***deleted***

that such an extension is justified by the research and development programme.

Amendment 62
Article 7, paragraph 8

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.	***deleted***
When taking decisions as provided for in paragraphs 4 and 7, the Agency shall take into account any comments made by such competent authorities.	

Amendment 63
Article 7, paragraph 9

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.	***deleted***

Amendment 64
Article 7, paragraph 10

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

Amendment 65
Article 8, title

Substances in plant protection and biocidal products	***deleted***

Amendment 66
Article 8, paragraph 1

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.	***deleted***

Amendment 67
Article 8, paragraph 2

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.	***deleted***

Amendment 68
Article 9, point (a) (iii)

(iii) information on the manufacture and use(s) of the substance as specified in	(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);***	section 3 of Annex IV; this information shall represent ***at least:***
	- all the registrant's identified categories of use;
	- the exposure categories;
	- the risk category established by the Agency on the basis of the pre-registration data;
	- all other risk-relevant data known to the producer or importer.

Justification

Requirement to submit categories of use and exposure categories as part of the registration process, as a prerequisite for risk-related evaluation and authorisation (including data requirements) and also for simpler communication along the product chain.

Amendment 69
Article 9, point (a) (vi)

(vi) summaries of the information derived from the application of Annexes V ***to*** IX;	(vi) summaries of the information derived from the application of Annexes V**, VI *and*** IX;

Justification

The new Annex V covers the core information (see Article 3(30) (new), Annex VI (combining, in summarised form, the original Annexes VI to VIII, as a selection for further tests). This is all the information that is necessary for a risk assessment.

Amendment 70
Article 9, point (a) (vii)

(vii) robust study summaries of the information derived from the application of Annexes V to IX, if required under Annex I;	***deleted***

Justification

SMEs, in particular, cannot be expected to submit comprehensive robust study summaries. The submission of summaries pursuant to Article 9(a)(vi) is sufficient.

Amendment 71
Article 9, point (a) (x)

(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;	(x) a declaration as to whether he agrees that his summaries of the information derived from the application of Annexes V ***and VI*** with regard to tests not involving vertebrate animals may be shared against payment with subsequent registrants;

Justification

Amendment follows from Article 9(a)(vii).

Amendment 72
Article 9, paragraph (b)

(b) a chemical safety report when required under Article 13.	(b) a chemical safety report when required under Article 13. ***This may be incorporated in a Safety Data Sheet, and generic exposure categories may be used to report exposure conditions.***

Justification

To facilitate control and simplify the workload of the whole EU industry, an extended SDS could be sufficient as a Chemical Safety report. Additionally, regarding the exposure conditions, simple categories of exposure should be defined for potential use by downstream users.

Amendment 73
Article 9, paragraph (ba) (new)

	(ba) Information required by this Article that has already been generated under other EU legislation or in conformity with internationally agreed conventions may be submitted in its original format so as to permit maximum utilisation of pre-existing procedures and data.

Justification

To reduce unnecessary administrative tasks and make REACH more workable, data which have been already collected on a certain number of substances under other EU or international programmes/legislation could be submitted as such and it should not be required to modify the dossier according to the REACH format.

Amendment 74
Article 9, point (b a) (new)

(ba) For purposes of compliance with paragraph (a), complete chemical dossiers for a chemical substance or a group of chemical substances submitted under the Organization for Economic Cooperation and Development Council Act on High Production Volume (HPV) Chemicals, the International Council of Chemical Associations HPV Initiative, or the U.S. Environmental Protection Agency HPV Challenge shall be presumed to meet the requirements of subparagraphs (a) (vi)-(x).

Justification

The OECD's Screening Information Data Set uses scientifically recognised principles to provide enough information to make initial hazard assessments of HPV chemicals. EU and US initiatives for existing HPV chemicals are based on these requirements. The use of data developed under internationally recognised protocols will streamline the development of information on the effects and safe use of substances, prevent unnecessary duplicative and costly development of data, particularly where it would result in tests on vertebrate animals, and inform the public more quickly.

Amendment 75
Article 10, paragraph 1, subparagraph 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 join in a consortium for the purposes of registration. Parts of the registration shall then be submitted by one manufacturer or importer	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 join in a consortium for the purposes of registration. Parts of the registration shall then be submitted by one manufacturer or importer

acting, with their agreement, on behalf of other manufacturers and/or importers in the following way:	***or a third party*** acting, with their agreement, on behalf of other manufacturers and/or importers in the following way:

Justification

To oblige a group of manufacturers of a substance to share information might violate confidentiality and thereby jeopardise joint submission of data. This problem can be avoided by a separate organisation or a third party contracted on behalf of a consortium representing the interest of the group of manufacturers.

Amendment 76
Article 10, paragraph 1, subparagraph 3

The one manufacturer or importer submitting on behalf of the other participants of the consortium shall submit the information specified in Article 9 (1) (a) (iv), (vi), (vii) and (ix).	The one manufacturer or importer ***or a third party*** submitting on behalf of the other participants of the consortium shall submit the information specified in Article 9 (1) (a) (iv), (vi), (vii) and (ix).

Justification

To oblige a group of manufacturers of a substance to share information might violate confidentiality and thereby jeopardise joint submission of data. This problem can be avoided by a separate organisation or a third party contracted on behalf of a consortium representing the interest of the group of manufacturers.

Amendment 77
Article 10, paragraph 1, subparagraph 4

The participants of the consortium may decide themselves whether they submit the information specified in Article 9 (1) (a) (v) and (b) separately or whether the one manufacturer or importer submits this information on behalf of the others.	The participants of the consortium may decide themselves whether they submit the information specified in Article 9 (1) (a) (v) and (b) separately or whether the one manufacturer or importer ***or a third party*** submits this information on behalf of the others.

Justification

To oblige a group of manufacturers of a substance to share information might violate confidentiality and thereby jeopardise joint submission of data. This problem can be avoided by a separate organisation or a third party contracted on behalf of a consortium representing the interest of the group of manufacturers.

Amendment 78
Article 10, paragraph 2

2. Each ***registrant who is a member of a*** consortium shall ***pay only one-third*** of the fee for registration.	2. Each consortium shall ***decide internally on the division*** of the fee for registration. ***Each registrant or consortium that has paid the fee for registration shall have the right to charge, at his/its own discretion and at the rate which he/it may decide, others who wish to participate in the registration of the substance. It shall therefore be possible for enterprises or consortiums themselves to determine the distribution of costs of registration.***

Justification

Within voluntarily formed consortia, members must themselves have the power to divide the costs.

Amendment 79
Article 11

Information to be submitted depending on tonnage	***deleted***
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:	
(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;	
(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;	
(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;

(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.

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.

Justification

Volume-related information requirements are no longer necessary, since the requirements will be exposure-related (Annex IXa).

It is clear, particularly in view of the requirements arising from the WTO TBT agreement, that the volume of substances alone is an unsuitable approach to regulation for determining general data requirements.

Amendment 80
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 81
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 categories of use/exposure***

categories of the manufacturer or importer.

Amendment 82
Article 13, paragraph 4a (new)

4a. The exposure assessment does not need to include:

(a) exposure of man if the hazard assessment concludes that the substance only meets the classification criteria for being hazardous to the environment;

(b) exposure of the environment if the hazard assessment concludes that the substance only meets the classification criteria for being hazardous to human health.

Justification

The information requested should be exposure driven. If there is no hazard, there is no risk and where there is risk to either environment or health, the information requested should be limited to the relevant compartment in question (either environment or health and not to both). This would efficiently prioritise information and remove an unnecessary burden.

Amendment 83
Article 13 paragraph 5

5.The chemical safety report need not include consideration of the risks to human health from the following end uses: ***a) in food contact materials within the scope of Council Directive 89/109/EEC;*** ***b) in cosmetic products within the scope of Council Directive 76/768/EEC.***	***deleted***

Justification

See amendments to Article 2, paragraph 1 c f (new) and Article 2, paragraph 1 c i (new).

Amendment 84
Article 13, paragraph 7 a (new)

	7a. Any manufacturer or importer of a substance or preparation who supplies that substance or preparation to a downstream user shall, at the request of that downstream user, in so far as this may reasonably be required, furnish the information necessary to assess the effects of the substance or the preparation on human health or the environment with respect to the operations and uses indicated in that request.

Justification

For a workable REACH the information must be distributed through the supply chain (upwards and downwards) to enable the companies to take appropriate actions and to make informed decisions. The downstream user's right to information is crucial in order to rebuild consumer confidence and to regain goodwill.

Amendment 85
Article 13, paragraph 7 b (new)

	7b. Any downstream user shall, at the request of his supplier, in so far as this may reasonably be required, furnish information necessary for the supplier to assess the effects of the substance or the preparation on human health or the environment as a result of the operations and use of the downstream user.

Justification

For a workable REACH the information must be distributed through the supply chain (upwards and downwards) to enable the companies to take appropriate actions and to make informed decisions. The downstream user's right to information is crucial in order to rebuild consumer confidence and to regain goodwill.

Amendment 86
Article 15

Registration of on-site isolated intermediates ***1. Any manufacturer of an on-site isolated intermediate in quantities of 1 tonne or***	***deleted***

more per year shall submit a registration to the Agency for the on-site isolated intermediate.

2. 2. A registration for an on-site isolated intermediate shall include all the following information, in the format specified by the Agency in accordance with Article 108, to the extent that the manufacturer is able to submit it without any additional testing:

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

(b) the identity of the intermediate as specified in section 2 of Annex IV;

(c) the classification of the intermediate;

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

Justification

Combined with Article 16.

Amendment 87
Article 16, paragraph 1

1. Any manufacturer or importer of ***a*** transported isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.	1. Any manufacturer or importer of ***an on-site or*** transported isolated intermediate in quantities of 1 tonne or more per year shall submit a registration to the Agency for the transported isolated intermediate.

Amendment 88
Article 16, paragraph 2, point (b)

(b) ***the identity*** of the intermediate ***as specified in section 2 of Annex IV***;	(b) ***name*** of the intermediate***, including the CAS number, if available***;

Justification

The precise determination of identity requires costly analytical investigation. It should be required only in particular cases, e.g. consortia.

Amendment 89
Article 16, paragraph 2, point (c)

(c) the classification of the intermediate;	(c) the classification of the intermediate***, if available***;

Justification

A classification is normally only necessary for intermediates which are placed on the market.

Amendment 90
Article 16, paragraph 3

3. A registration for a transported isolated intermediate in quantities of more than 1 000 tonnes per year shall include the information specified in Annex V in addition to the information required under paragraph 2.	***deleted***
For the generation of this information, Article 12 shall apply.	

Justification

Fundamental abandonment of the quantity-related approach.

Amendment 91
Article 16, paragraph 4, point (a), (b), (c), (d), (e), (f), (g), and (h)

(a) the substance is rigorously contained by technical means during its whole lifecycle including manufacture, transportation (including transport by rail, road, inland waterway, sea or air and pipeline transfer), purification, cleaning and maintenance, sampling, analysis, loading and unloading of equipment or vessels, waste disposal or purification and storage;	***deleted***
(b) where there is potential for exposure, procedural and control technologies are available which minimise emission and the	

resulting exposure;

(c) only properly trained and authorised personnel handle the substance;

(d) in the case of cleaning and maintenance works, special procedures such as purging and washing are applied before the system is opened and entered;

(e) transport operations are in compliance with the requirements of Directive 94/55/EC;

(f) in cases of accident and where waste is generated, procedural and/or control technologies are used to minimise emissions and the resulting exposure during purification or cleaning and maintenance procedures;

(g) substance-handling procedures are well documented and strictly supervised by the site operator;

(h) the registrant operates a system of product stewardship and monitors users to ensure compliance with the conditions listed in points (a) to (g).

If the conditions listed in the first subparagraph are not fulfilled, the registration shall include the information specified in Article 9.

Justification

Requirements concerning controlled conditions should be laid down in separate guidelines. The conditions laid down in the proposal are to inflexible and are not sufficiently geared to practical circumstances.

Amendment 92
Article 17

Joint submission of data by members of consortia ***deleted***

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.	
Each member of the consortium shall submit separately the information specified in Article 15(2)(a) and (b) and Article 16(2)(a) and (b).	
The one manufacturer or importer submitting on behalf of the other members of the consortium shall submit the information specified in Article 15(2)(c) and (d) and Article 16(2)(c) and (d) and (3), where relevant.	
2. Each registrant who is a member of a consortium shall pay only one-third of the fee.	

Justification

Registration of intermediates will no longer be required. If pre-registration or the sharing of data is required, Article 10 will apply.

Amendment 93
Article 19, paragraph 1, second subparagraph

A registrant may start the manufacture or import of a substance, ***if there is no indication to the contrary from the Agency*** in accordance with Article 18(2) within the three weeks after the registration date, without prejudice to the fourth subparagraph of Article 25(4).	A registrant may start ***and/or continue*** the manufacture or import of a substance, ***until the Agency indicates otherwise*** in accordance with Article 18(2) within the three weeks after the registration date, without prejudice to the fourth subparagraph of Article 25(4).

Justification

Paragraph 2 indicates that all production needs to stop until further notice. This will disturb the market and the business policies of companies. Production lines need to continue until the

agency indicates otherwise. Deselection from the market or for specific uses would affect a large number of preparations and production recipes requiring lengthy reformulation and validation work. Consequently, time is needed for downstream users to reformulate and validate new recipes while continuing to produce. This can only be achieved if the suppliers are allowed a period of grace pending a deadline by which they will phase out the substance.

Amendment 94
Article 19, paragraph 1, new final subparagraph

For phase-in substances not being registered including for a specific use the manufacturer or importer in question shall have 36 months to phase out the substance from the market including for that specific use after the deadlines referred to in Article 21.

Justification

Linked to the amendment to Article 19, paragraph 1, second subparagraph.

Amendment 95
Article 20, paragraph 1, point (c)

(c) significant changes in the annual or total quantities manufactured or imported by him;	***deleted***

Justification

Consistent deletion of all quantity-related requirements.

Amendment 96
Article 20, paragraph 1, point d

(d) new uses for which the substance is manufactured or imported of which he ***may reasonably be expected to have become*** aware;	(d) new uses ***or categories of use/exposure categories*** for which the substance is manufactured or imported of which he ***is*** aware ***and which he supports***;

Justification

The phrase 'of which he may reasonably be expected' is impracticable. The manufacturer/importer must not be obliged to report applications that he does not support.

Amendment 97
Article 20, paragraph 2

2. In cases covered by Articles 10 or 17, each registrant shall submit separately the information specified in paragraph 1(c).	***deleted***

Justification

Consistent deletion of all quantity-related requirements.

Amendment 98
Chapter 6, Title

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

Amendment 99
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, 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 100
CHAPTER 1 (new)

PRINCIPLES

Amendment 101
Article 20 a (new)

	Article 20a
	Scope of transitional provisions
	The transitional provisions of this Title may be used only for phase-in substances for which a manufacturer or importer has received a pre-registration number.

Amendment 102
Article 21, paragraph 1

1. Article 19 shall not apply to ***the following*** substances for a period of ***3*** years after the entry into force of this Regulation***:***	1. Article 19 shall not apply to ***phase-in*** substances ***in the first processing list (Article 22e)*** for a period of ***five*** years after the entry into force of this Regulation***.***
(a) phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC and manufactured in the Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation;	
(b) phase-in substances manufactured in the Community or imported, in quantities reaching 1 000 tonnes or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation.	

Amendment 103
Article 21, paragraph 2

2. Article 19 shall not apply for a period of ***6*** years after entry into force of this Regulation to phase-in substances ***manufactured*** in the ***Community or imported, in quantities reaching 100 tonnes or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation***.	2. Article 19 shall not apply for a period of ***seven*** years after *the* entry into force of this Regulation to phase-in substances in the ***second processing list (Article 22f(1))***.

Amendment 104
Article 21, paragraph 2 a (new)

	2a. Article 19 shall not apply for a period of nine years after the entry into force of this Regulation to phase-in substances in the third processing list (Article 22f(2)).

Amendment 105
Article 21, paragraph 3

3. Article 19 shall not apply for a period of 11 years after entry into force of this Regulation to phase-in substances ***manufactured*** in the ***Community or imported, in quantities reaching 1 tonne or more per year per manufacturer or per importer, at least once following the entry into force of this Regulation***.	3. Article 19 shall not apply for a period of 11 years after *the* entry into force of this Regulation to phase-in substances in the ***fourth processing list (Article 22f(3))***.

Amendment 106
Article 21, paragraph 3 a (new)

	3a. Recourse to the transitional provisions laid down in paragraphs 1 to 3 shall require the potential registrant of a phase-in substance to have notified that substance to the register of substances pursuant to

Article 22a, with the data required therein and within the periods laid down therein, and to have received a pre-registration number accordingly.

Amendment 107
Article 21, paragraph 3 b (new)

3b. The right of recourse to the transitional provisions laid down in paragraphs 1 to 3 shall lapse if the registrant fails to submit the core information referred to in Article 22c in respect of the substance notified to the register of substances; the lapsing of the right of recourse to the transitional provisions laid down in paragraphs 1 to 4 shall also result in the pre-registration number assigned pursuant to Article 22e(4) ceasing to be valid. The preceding sentence shall not apply to substances in the first processing list (Article 22e).

Amendment 108
Article 21, paragraph 3 c (new)

3c. Paragraph 3b shall not apply to on-site and transported isolated intermediates.

Amendment 109
Article 21, paragraph 3 d (new)

3d. For the purpose of phasing in the system of managing chemical substances in articles pursuant to Article 6 in conjunction with Article 54 (a)-(f), sector-specific

	guidance should be introduced as a voluntary tool six years after entry into force of the regulation.

Justification

To achieve a functional system to manage the use of authorised chemicals in the supply chain, it is necessary to apply a three-phase model. This will ensure a smooth transition, including for SMEs.

Amendment 110
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[1] 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.*** _____ ***1 OJ L 84, 5.04.1993, p.1***

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.

Amendment 111
Article 22, paragraph 2

2. ***If the quantity of a notified substance manufactured or imported per manufacturer or importer reaches the next***	2. ***Article 20 shall apply to substances which are regarded as having been***

tonnage threshold under Article 11, the additional required information corresponding to ***that tonnage threshold,*** as ***well as*** to ***all the lower tonnage thresholds, shall be submitted in accordance with Articles 9 and 11, unless it has already been submitted in accordance with those Articles.***	***registered pursuant to paragraph 1.***

Justification

The reference to tonnage threshold is superfluous (see Justification to Art. 11). Only the notification obligations under Art. 20 are to be observed.

Amendment 112
CHAPTER 1 a (new), Title

PRE-REGISTRATION

Amendment 113
Article 22 a (new), title

Article 22a

Obligation to notify substances to the register of substances

Justification

The new Title IIa will ensure that firms submit core information (see Article 22c) in connection with the establishment of the inventory of substances (see Article 3(20)). That information contains the most important details regarding the properties of, exposure to and use of substances. This basis will permit prioritisation, with staggered processing lists for subsequent registration.

Amendment 114
Article 22 a (new), paragraph 1

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 substance, either on its own or in a preparation, must

communicate to the Agency, for inclusion in the register of substances, the information referred to in paragraph 2.

Justification

This right of application is particularly relevant to downstream users who find, after the expiry of the period for notification to the register of substances, that an important substance has not been notified by their supplier. There is the opportunity to find another supplier during the late notification period and have a late notification submitted for the substance, or for the user to notify it himself.

Amendment 115
Article 22 a (new), 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;

(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;

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

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

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

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

Amendment 116

Article 22 a (new), paragraph 3

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. In the case of late notification the period for communication of the core information shall be that laid down in Article 22c. 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.

Amendment 117
Article 22 a (new), paragraph 4

4. The Agency must 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. The Agency must inform the manufacturer or importer of the pre-registration number and the date of receipt without delay, and in doing so must inform the manufacturer or importer of the notification obligations pursuant to Article 22c and of the consequences of failure to comply with those obligations or default.

The pre-registration number shall serve as evidence of the provisional right to manufacture or import the substance within the meaning of Article 21.

Justification

For the purposes of prioritisation the key factors are the toxic properties of substances, the extent of exposure and the production volume. Each substance will be included in one of the processing lists on that basis and called for registration at a certain point. This will ensure that a higher degree of safety is reached more speedily, and will also facilitate the establishment of consortia.

Amendment 118
Article 22 a (new), paragraph 5

5. Paragraph 4 shall apply by analogy to on-site and transported isolated intermediates provided that the Agency assigns a registration number within the meaning of Article 18(1) for the notification to the register of substances.

Amendment 119
Article 22 a (new), paragraph 6

6. 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 30 days after the expiry of the period referred to in the first sentence of paragraph 5.

Amendment 120
Article 22 b (new)

Article 22b

Register of substances

Justification

The publication of the list/inventory of substances by the Agency will ensure a high degree of transparency at an early stage.

Amendment 121

Article 22 b (new), paragraph 1

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

Amendment 122
Article 22 b (new), paragraph 2

2. The Agency shall publish all notified substances in the register of substances one month after the expiry of the notification period laid down in Article 22a(1), indicating:

Amendment 123
Article 22 b (new), paragraph 2, subparagraph a

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

Amendment 124
Article 22 b (new), paragraph 2, subparagraph b

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

Amendment 125
Article 22 b (new), paragraph 2, subparagraph c

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

Amendment 126
Article 22 b (new), paragraph 3

3. 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.

Amendment 127
Article 22 c (new), title

Article 22c

Core information

Amendment 128
Article 22 c (new), paragraph 1

1. Each manufacturer or importer of a substance included in the register of substances must submit core information for each substance, in accordance with paragraph 2, to the Agency within 3 years and 6 months of the publication of the register of substances pursuant to Article 22b(2). The preceding sentence shall not apply to substances in the first processing list (Article 22e).

Amendment 129
Article 22 c (new), paragraph 2

2. The following information must be notified as core information in the format specified by the Agency in accordance with

Article 108:

Amendment 130
Article 22 c (new), paragraph 2, subparagraph a

(a) information about the properties of the substance in accordance with Annex V;

Amendment 131
Article 22 c (new), paragraph 2, subparagraph b

(b) the classification and labelling, if available;

Amendment 132
Article 22 c (new), paragraph 2, subparagraph c

(c) information about the categories of use;

Amendment 133
Article 22 c (new), paragraph 2, subparagraph d

(d) information about exposure;

Amendment 134
Article 22 c (new), paragraph 2, subparagraph e

(e) inclusion in the second processing list pursuant to Article 22f(1)(b), if necessary.

Amendment 135
Article 22 c (new), paragraph 3

3. If the period referred to in paragraph 1 has elapsed the Agency may, in justified cases, permit the late notification of core information and of the information pursuant to Article 22a(2), in accordance with paragraph 2, for an application made in respect of a substance listed in the register of substances within a late notification period of a further six months. In that case the Agency shall assign a pre-registration number to the manufacturer/ importer who submits the information referred to above.

Amendment 136
Article 22 c (new), paragraph 4

4. With the exception of monomers which are used as on-site or transported isolated intermediates, paragraphs 1 to 5 shall not apply to on-site and transported isolated intermediates. However, the manufacturers or importers of those substances must draw up the information referred to in paragraph 2(a) relating to the properties of the substance in accordance with Annex V, with the exception of information about sensitisation; this information must be kept available for the competent authorities in connection with official controls (Article 122) and also for the Agency, upon request.

Amendment 137
Article 22 c (new), paragraph 5

5. Article 10 and Article 18(2), first and third sentences et seq., (3) and (4) shall apply by analogy.

Amendment 138
CHAPTER 3 (new), title

PRIORITISATION IN RESPECT OF REGISTRATION DURING THE TRANSITIONAL PERIOD

Amendment 139
Article 22 e (new)

Article 22e (new)
Substances in the first processing list

1. Substances in the first processing list must be registered within five years of the entry into force of this Regulation.

2. The first processing list, and any supplements or modifications thereto, shall be published in accordance with Article 22b(2)(d), in conjunction with publication of the register of substances.

Amendment 140
Article 22 f (new)

Article 22f (new)
Substances in the second, third and fourth processing lists

1. Substances in the second processing list must be registered within seven years of the entry into force of this Regulation.

2. Substances in the third processing list must be registered within nine years of the entry into force of this Regulation.

	3. Substances in the fourth processing list must be registered within 11 years of the entry into force of this Regulation.
	4. The Agency shall publish the second, third and fourth processing lists within one month of the expiry of the period referred to in Article 22c(1) for the notification of core information. Where permitted late notifications of core information (Article 22c(3)) pursuant to Article 22d(2), second sentence and Article 22d(3) result in the processing lists being supplemented or modified, the Agency shall publish such supplements or modifications within one month of the expiry of the late notification period referred to in Article 22c(3).

Amendment 141
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) ***the share*** of the cost ***calculated according to paragraph 8a***.

Amendment 142
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	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.	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 ***the share*** of the cost ***calculated according to paragraph 8a***, which shall be enforceable in the national courts.

Amendment 143
Article 25, paragraph 8 a (new)

	8a. The Agency shall open a current account for all registrants. The cost of the first registration shall be checked by the Agency. Any future registrant sharing or benefiting from the original registration will have to pay the equivalent to its share of the initial total cost, meaning that each registrant that enters will lower its own entrance cost and, simultaneously, that of those already registered. Those already registered will be reimbursed (credited) to the extent of their share in the cost reduction brought by the new registrant.

Justification

The purpose is that every registrant will be interested in sharing his registration as soon as possible with as many people as possible in order to lower his financial burden.

Amendment 144
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

Deleted from Title III because preregistration should, as a matter of course, be regulated in Title IIa on registration (see in particular Articles 20a and 22 of the latter title). From the point of view of reducing animal experiments, preregistration is unnecessary.

Amendment 145
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 22a*** for the same phase-in substance shall be participants in a substance information exchange forum (SIEF).

Justification

Downstream users should have access to SIEF to share hazard & exposure data. Follows from previous amendments, since Article 26 is to be deleted. The information must now be notified under Article 22a in the substance register.

Amendment 146
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	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 ***within two months of the deadline set in Article 26(2)***.	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 147
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 ***or about categories of use and exposure categories*** 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.

Amendment 148
Article 28 a (new)

	Article 28a (new) ***Competence and legal protection***
	1. The Agency shall be competent to take decisions under this Title save as otherwise provided.
	2. An appeal against Agency decisions under this Title may be brought in accordance with Articles 87, 88, and 89.

Justification

For clarity, it should be expressly stated that the Agency is competent for the purposes of Title III as a whole. Rather than listing cases as and where they arise, the right of appeal should be laid down in one place.

Amendment 149
Article 29, paragraph 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 150
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 ***use and exposure categories including a description of the*** exposure scenarios shall be placed in an annex to the safety data sheet ***and/or shall be made available for consultation electronically***.

Justification

UEC are the main instrument for the structured transfer of information on risk management measures, exposure target values (e.g. DNEL, PNEC) and conditions of use along the supply chain. They support the actors in the supply chain in their own risk assessment and in the establishment of a safety data sheet for the subsequent actors in the supply chain.

Amendment 151
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 ***exposure categories***, a downstream user shall use appropriate information from the safety data sheet supplied to him.

Justification

It is unnecessary for safety data sheets to have to be sent out again purely because the regulation had entered into force, even when users already had them.

Amendment 152
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 Regulation. Suppliers shall update it without delay on the following occasions:	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 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

See justification to amendment to Article 29, paragraph 7.

Amendment 153
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 154
Article 30 a (new)

Article 30a
Duty to communicate information on substances in articles

1. An actor upstream in the supply chain who incorporates in an article a substance, on its own or in a preparation, that meets the criteria for authorisation according to points (a) to (f) of Article 54 and/or for classification as dangerous according to Directive 67/548 shall provide upon request information that the substance is present in the article to an actor down the supply chain.

2. The Commission shall decide on the forms for providing the information referred to in this article according to the procedure referred to in Article 130(3).

3. A producer or importer of an article shall provide the following information to a consumer, if the consumer requests it:

(a) whether the article contains any substances meeting the criteria for authorisation according to Article 54;

(b) if so, which of those substances are contained in the article.

Justification

REACH demands an information flow through the supply chain from the chemical producer to downstream users of chemicals. However, the information flow stops when a chemical enters an article. This amendment makes sure that actors further down the supply chain for articles receive information which makes it possible to contribute to better risk management of uses of chemicals in articles. This information is further necessary for producers/users of articles in order to comply with other EC legislation (e.g. product safety directive, toys directive) and to provide information to consumers.

Amendment 155
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 ***as referred to in Article 3(25) and Article 3 (30)***. 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.

A downstream user should be able to indicate one or more additional use and exposure categories to his supplier. The use and exposure categories should be the basis for the information along the supply chain. UEC are the main instrument for the structured transfer of information on risk management measures, exposure target values (e.g. DNEL, PNEC) and conditions of use along the supply chain. They support the actors in the supply chain in their own risk assessment and in the establishment of a safety data sheet for the subsequent actors in the supply chain.

Amendment 156
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.	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, ***concerning a use, categories of use, or exposure categories,*** 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.

Amendment 157
Article 34, paragraph 4

4. A downstream user of a substance on its own or in a preparation shall prepare a	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.	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.

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.

Amendment 158
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 exposure scenario***.	1. Before commencing a particular use of a substance ***in accordance with a category of use or exposure category*** 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***, category of use, or exposure category*** and the downstream user is using the substance outside the conditions described ***therein***.

Amendment 159
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 160
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. For the purposes of Articles 39 to ***46***, the competent authority shall be the ***Agency***. ***However, a number of procedures may be delegated by protocol to the competent authorities of the Member States.***

Justification

In order to create a true level playing field, the Agency must be given a broader mandate and responsibilities. Hence, the Agency should be responsible for evaluation at the Community level, assisted and advised by Member State authorities and the Member State Committee which is the technical advisory body under the REACH system. It is important to create a level playing field between Member State authorities.

Amendment 161
Article 38, paragraph 1 a (new)

	1a. For the purposes of Articles 39 to 43, whenever appropriate an opinion should be requested from the Member State Committee referred to in Article 72(e).

Justification

The Agency shall work using advice from and in cooperation with the Member State authorities, but shall retain full responsibility for any decision taken.

Amendment 162
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.	***deleted***

Amendment 163
Article 39

Examination of testing proposals	***deleted***
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.	
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:	
(a) a decision requiring the registrant(s) or downstream user(s) concerned to carry out the proposed test and setting a deadline for submission of the summary of the test result, or the robust study summary if required by Annex I;	
(b) a decision in accordance with point (a), but modifying the conditions under which the test is to be carried out;	
(c) a decision rejecting the testing proposal.	
3. The registrant shall submit the information required to the Agency.	

Justification

Testing proposals will not need to be submitted, because all information relevant to safe use will have already been provided at the time of registration. The competent authority/Agency will consequently not be called upon to examine such proposals.

Amendment 164
Article 40, paragraph 1, introductory part

1. The ***competent authority*** may examine any registration in order to verify either or both of the following:	1. The ***Agency*** may examine any registration in order to verify the following:

Amendment 165
Article 40, paragraph 1, point a

(a) that the information in the technical dossier(s) submitted pursuant to ***Article 9***	(a) that the information in the technical dossier(s) submitted pursuant to ***Articles 9,***

complies with the requirements of ***Articles 9, 11 and 12*** and with ***Annexes IV to VIII***;	***12, and 13*** complies with the requirements of ***those*** Articles and with ***the related Annexes***;

Amendment 166
Article 40, paragraph 1, point b

(b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes V to VIII and with the general rules set out in Annex IX.	***deleted***

Justification

The Agency should be allowed to examine all documents submitted.

Amendment 167
Article 40, paragraph 2

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 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.

Amendment 168
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 ***Article 40***, and draft any appropriate decisions in accordance with ***Article 40***, if necessary.

Amendment 169

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 inform the Commission, the registrant and the competent authorities of the Member States on its conclusions as to whether or how to use the information obtained ***for the purposes of Articles 56(3) and 66(2)***.

Justification

Information obtained from evaluations might be of use for registration procedures or restrictions processes.

Amendment 170
Article 42

Procedure and time periods for examination of testing proposals	***deleted***
1. A competent authority that starts evaluating a testing proposal under Article 39 shall notify the Agency accordingly.	
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.	
3. In the case of phase-in substances, the competent authority shall prepare the draft decisions in accordance with Article 39(2):	
(a) within 5 years of the entry into force of this Regulation for all registrations received within the deadline referred to in Article 21(1) containing proposals for testing in order to fulfil the information requirements in Annexes VII and VIII;	

(b) within 9 years of the entry into force of this Regulation for all registrations received within the deadline referred to in Article 21(2) containing proposals for testing in order to fulfil the information requirements in Annex VII only;

(c) after the deadlines set in points (a) and (b) for any registrations containing testing proposals received within the deadline referred to in Article 21(3).

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.

Justification

All information relevant to safe use will have already been provided at the time of registration. Testing proposals will not therefore need to be submitted nor need the Agency be notified.

Amendment 171
Article 43, paragraph 1

1. A competent authority that starts evaluating the compliance of a registration under Article 40 shall notify the Agency accordingly.	***deleted***

Justification

Testing proposals will not need to be submitted, because all information relevant to safe use will have already been provided at the time of registration.

Amendment 172
Article 43, paragraph 2

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.

Amendment 173
Article 43, paragraph 3

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.	***deleted***

Amendment 174
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 ***consistent and transparent*** approach, the Agency shall develop ***risk-based*** criteria for decisions ***on the selection of*** substances ***for substance*** evaluation. The criteria for evaluation shall include consideration of hazard data, exposure data***, and recommended risk management measures***. ***They shall list the circumstances under which information supplied pursuant to Title II and dossier evaluation within the meaning of Title VI are insufficient for risk assessment and risk management regarding a substance and its identified use(s).***

Justification

The Agency must have criteria in order to justify any decisions on further evaluation, and such justifications must be based on transparent considerations.

Amendment 175
Article 43aa, paragraph 1

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***	1. ***Where the Agency considers substance evaluation to be necessary, it shall take a decision in accordance with Articles 43a, 48, and 49.***

environment, in particular on the basis of either of the following:	
	If it decides to carry out an evaluation, it shall include the substance concerned in a rolling plan for the purposes of Articles 44 to 46. Priority shall be assigned to the plan in the light of the risk posed.
(a) structural similarity of the substance with known substances of concern or with substances which are persistent and liable to bio-accumulate, suggesting that the substance or one or more of its transformation products has properties of concern or is persistent and liable to bio-accumulate;	
(b) aggregated tonnage from the registrations submitted by several registrants.	

Justification

Substance evaluation cannot be set in motion unless the criteria set out in Article 43 are met,

Amendment 176
Article 43aa, 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 ***Community*** rolling plan as referred to in paragraph 1 shall cover a period of three years, updated annually, and shall specify the substances which ***each*** Member State ***will be asked*** to evaluate each year. The ***Agency*** shall submit the ***Community*** rolling plan to the Member ***States' authorities*** by 28 February each year. Member States may send their comments to the Agency or express their interest in evaluating a substance by 31 March of each year.

Justification

The Agency should be responsible for drawing up Community rolling plans for substance evaluations. The actual evaluations will subsequently be distributed to national authorities on

the basis of know-how. This will ensure the best use of the available resources on the Community level.

Amendment 177
Article 43aa, 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 a ***Community*** rolling plan, this rolling plan ***shall be deemed adopted***. The competent authority shall be the competent authority of the Member State ***to which the Agency has assigned the task of carrying out*** the substance ***evaluation*** in ***the*** definitive ***Community*** rolling plan.

Justification

After establishing the Community rolling plan for substance evaluation, the Agency will distribute the substance evaluations to Member State authorities on the basis of know-how.

Amendment 178
Article 43aa, 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.	4. In cases where two or more Member States 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.
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***	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 ***technical capacity to develop the Community rolling plan and an equally balanced share among EU Member States of the technical capacity building spill-overs deriving from the***

question under Articles 39 to 43.	***REACH directive.***
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, within 60 days of the referral, the Member State Committee reaches unanimous agreement, the ***Agency*** shall adopt ***the*** definitive ***Community*** rolling ***plan*** accordingly.
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.	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 ***Agency*** shall adopt ***the*** definitive ***Community*** rolling ***plan*** accordingly.

Justification

Self-evident when the Agency is given responsibility for establishing the Community rolling plan.

Amendment 179
Article 43aa, paragraph 5

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

Amendment 180
Article 43aa, 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.	6. The competent authority identified in accordance with paragraphs ***3 and*** 4 shall evaluate all substances ***assigned to it*** in accordance with this Chapter.

Amendment 181
Article 44, paragraph 1

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 ***beyond the requirements under Articles 9, 12, and 13***, 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.

Justification

In justified individual cases the Agency may decide to impose wider-ranging information requirements.

Amendment 182
Article 44, paragraph 4

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 ***registrant(s)*** 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.

Amendment 183
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*** 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.

Amendment 184
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	***deleted***

appropriate, implementing measures shall be adopted in accordance with the procedure referred to in Article 130(3).

Justification

Follows from previous amendments, since responsibility now lies with the Agency as opposed to any national authority.

Amendment 185
Article 46, paragraph 1

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.

Amendment 186
Article 46, paragraph 2

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. The ***Agency*** shall inform the Commission, the registrant and the competent authorities of the other Member States of its conclusions as to whether or how to use the information obtained ***for the purposes of Articles 56(3) and 66(2)***.

Justification

Information obtained from evaluations might be of use for registration procedures or restrictions processes.

Amendment 187
Article 47

For on-site isolated intermediates, neither dossier nor substance evaluation shall	***The Agency may, also at the request of the competent authority of the Member State in***

apply. However, where a risk equivalent to the level of concern arising from the use of substances to be included in Annex XIII under Article 54 can be demonstrated arising from the use of an on-site isolated intermediate, the competent authority of the Member State in whose territory the site is located may:

(a) require the registrant to submit further information directly related to the risk identified. This request shall be accompanied by a written justification;

(b) examine any information submitted and, if necessary, take any appropriate risk reduction measures to address the risks identified in relation to the site in question.

The procedure provided for in the first paragraph may be undertaken only by the competent authority referred to therein.

whose territory the site in question is located, require information held in readiness on company premises in accordance with Article 16 to be submitted concerning intermediates. The Agency may evaluate that information in accordance with Article 40.

Justification

The Agency may, on its own initiative and at the justified request of the Member State's competent authority, also examine intermediates.

Amendment 188
Article 48, paragraph 1

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 40, 43 a bis, 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.

Amendment 189
Article 48, paragraph 2

2. If a registrant has ceased the manufacture or import of the substance, he shall inform the ***competent authority*** of this fact with the

2. If a registrant has ceased the manufacture or import of the substance, he shall inform the ***Agency*** of this fact with the consequence

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***.	that ***the rights deriving from the*** registration shall ***remain in abeyance and, while that is the case,*** no further information may be requested with respect to that substance. ***If the registrant ceases to manufacture or import the substance for good, his registration shall cease to be valid after three years, unless he transfers the rights under it to a third party before that period has expired.***

Justification

It often happens that manufacturing or importation ceases only temporarily. Automatic loss of validity of the registration would be unreasonable. Under the second sentence the registration will remain valid for a transitional period of three years to enable the registrant to assign his legal status to a third party (cf. Article 6b(1)).

Amendment 190
Article 48, paragraph 3

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.***	3. ***Paragraph 1 shall also apply if the registrant ceases to manufacture or import the substance after he has received the draft decision.***

Justification

The arrangement proposed should also apply in cases where a registrant no longer wishes to manufacture or import the substance after he has received the draft decision.

Amendment 191
Article 48, paragraph 4, point a

(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;

Amendment 192
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 ***its*** draft ***decisions***, together with ***any*** comments ***for the purposes of Articles 40, 41, 43, 43a bis, and 44,*** to the competent authorities of the Member States.

Justification

Consistent with Article 43a bis (1).

Amendment 193
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 propose amendments to the draft decision within the same period with a copy to the competent authority.***	2. Within 30 days of circulation, the competent authorities of the Member States may propose amendments to the draft decision to the Agency.

Justification

Follows from previous amendments, since responsibility lies with the Agency as opposed to any national authority.

Amendment 194
Article 49, paragraph 4

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***	4. If the Agency receives a proposal for amendment, it may modify the draft decision. The Agency shall ***consider the proposal and take*** a decision within 15 days of the end of the 30-day period referred to in paragraph 2.

proposal for amendment in accordance with paragraph 2.

Justification

Follows from previous amendments, since responsibility lies with the Agency as opposed to any national authority.

Amendment 195
Article 49, paragraph 5

5. The Agency shall forthwith communicate any proposal for amendment to any registrants or downstream users concerned and allow them to comment within 30 days. The Member State Committee shall take any comments received into account.	***deleted***

Amendment 196
Article 49, paragraph 6

6. If, within 60 days of the referral, the Member State Committee reaches a unanimous agreement on the draft decision, the Agency shall take the decision accordingly. ***If the Member State Committee fails to reach a unanimous agreement, it shall adopt an opinion in accordance with Article 81(8) within 60 days of the referral. The Agency shall transmit that opinion to the Commission.***	***deleted***

Amendment 197
Article 49, paragraph 7

7. Within 60 days of receipt of the opinion, the Commission shall prepare a draft decision to be taken in accordance with the procedure referred to in Article 130(2).	***deleted***

Amendment 198
Article 50

Cost sharing for tests involving vertebrate animals without an agreement between registrants	Cost sharing for tests involving vertebrate animals without an agreement between registrants
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 equally.
2. In the case referred to in paragraph 1, the registrant or downstream user who performs the test shall provide each of the others concerned with a copy of the test.	
3. The person performing and submitting the study shall have a claim against the others accordingly. The others shall have a claim for a copy of the study. Any person concerned shall be able to make a claim in order to prohibit another person from manufacturing, importing or placing the substance on the market if that other person either fails to pay his share of the cost or to provide security for that amount or fails to hand over a copy of the study performed. All claims shall be enforceable in the national courts. Any person may choose to submit their claims for remuneration to an arbitration board and accept the arbitration order.	

Amendment 199
Article 51, paragraph 1

Obligations ***for Member States to report to the Agency***	***Reporting*** obligations
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 report to on the progress made over the previous calendar year towards discharging ***its*** obligations in relation to the examination of testing proposals. The Agency shall publish this information on its *website* without delay.

Justification

Follows from previous amendments, since responsibility lies with the Agency as opposed to any national authority.

Amendment 200
Article 53, paragraph 1, point a

(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 has been authorised in accordance with Articles 57 to 61; or

Amendment 201
Article 53, paragraph 1, point b

(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 has been exempted from the authorisation requirement in Annex XIII itself in accordance with Article 55(2); or

Amendment 202
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 203
Article 53, paragraph 4

4. Paragraphs 1 and 2 shall not apply to the	4. Paragraphs 1 and 2 shall not apply to the

use of substances in scientific research and development or in product and process orientated research and development ***in quantities not exceeding 1 tonne per year***.	use of substances in scientific research and development or in product- and process-orientated research and development.

Justification

The quantities of substances used for scientific or product- and process-orientated research and development should not be limited to 1 tonne. This would inhibit innovation.

Amendment 204
Article 53, paragraph 5, point 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 205
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 206
Article 53 paragraph 5 (ib) new

(ib) uses of metals, including as alloys consistent with the exemption from labelling according to Dir. 67/548/EEC[1], Annex VI No. 8.3 and No 9.3.

1 OJ L 196 , 16/08/1967 p.1

Justification

The vast number of uses of metals, particularly in the form of alloys (there are around 30,000 alloys in commercial production), could lead to potential overwhelming of the authorisation process unless a simplified system is introduced. Like polymers, most metals and alloys in the massive form "pose a limited risk because of their nature". They should therefore be eligible normally for assessment via a simplified procedure unless there are indications of potential risks that justify more detailed evaluation of specific exposure scenarios.

Amendment 207
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.

Amendment 208
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 209
Article 55, paragraph 1, subparagraph (c) (i)

(i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted, hereinafter 'the sunset date';	(i) the date(s) from which the placing on the market and the use of the substance shall be prohibited unless an authorisation is granted, hereinafter 'the sunset date'***, taking into account application specific lead-times and product cycles***;

Justification

Timing of restriction/authorisation needs to take account of lead-times and product cycles that are application-specific. For some uses, legal limitations on substance use may be possible early, while more time is required for others given the lead-times and product cycles. So as to limit the cost and maximise benefits, decisions must take into account these factors.

Amendment 210
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 211
Article 55, paragraph 2

2. Uses or categories of use*s* 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 212
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 213
Article 57, paragraph 3, subparagraph (c)

(c) the analysis of the alternatives submitted by the applicant under Article 59(5) and any third party contributions submitted under Article 61(2);	(c) the analysis of the alternatives submitted by the applicant under Article 59(5) and any third party contributions ***that meet the standards of science and are*** submitted under Article 61(2);

Justification

The results of the cost-benefit analysis 'should' be taken into account. It is not sensible to make such an analysis and then disregard the results. The wording 'should' nevertheless still gives authorities the freedom to take decisions against the cost-benefit assessment. Third-party contributions can provide useful input if they meet the standards of science. Timing of restriction/authorisation needs to take account of lead-times and product cycles that are application-specific.

Amendment 214
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 may be subject to conditions, including review periods and/or monitoring. Authorisations granted in accordance with paragraph 3 shall normally be subject to a ***future review that takes into account application-specific lead times and product cycles.***

Justification

Linked to amendment to Article 57, paragraph 3(c). For some uses, legal limitations on substance use may be possible early, while more time is required for others given the lead-times and product cycles. So as to limit the cost and maximise benefits, decisions must take into account these factors. Cost considerations must play a role when deciding to what extent exposure is to be reduced.

Amendment 215
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 216
Article 57, paragraph 8

8. Notwithstanding any conditions of an authorisation, the holder shall ensure that the level of exposure is reduced to as low as is technically possible.	8. Notwithstanding any conditions of an authorisation, the holder shall ensure that the level of exposure is reduced to as low as is technically possible ***at reasonable costs***.

Justification

Linked to amendments to Article 57, paragraphs 3(c) and 6.

Amendment 217
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 218
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 219
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 220
Article 60, paragraph 2

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).	2. 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 221
Article 61, paragraph 4, point a

(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;

Amendment 222
Article 61, paragraph 4, point b

(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 223
Article 62

Holders of an authorisation shall include the authorisation number on the label before they place the substance on the market for an	Holders of an authorisation shall include the authorisation number on the label before they place the substance on the market for an

authorised use.	authorised use ***or categories of use or exposure categories***.

Amendment 224
Article 68, paragraph 1

1. Within 12 months of the date of publication referred to in Article 66(3), the Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to point (b) of Article 66(3), if there are any. The Agency shall publish the draft opinion on its website without delay. The Agency shall invite interested parties to give their comments on the draft opinion by a deadline set by the Agency.	1. Within 12 months of the date of publication referred to in Article 66(3), the Committee for Socio-economic Analysis shall formulate an opinion on the suggested restrictions, based on its consideration of the relevant parts of the dossier and the socio-economic impact. It shall prepare a draft opinion on the suggested restrictions and on the related socio-economic impact, taking account of the analyses or information according to point (b) of Article 66(3), if there are any. The Agency shall publish the draft opinion on its website without delay***, taking into account application-specific lead times and product cycles.*** The Agency shall invite interested parties to give their comments on the draft opinion by a deadline set by the Agency.

Justification

Timing of restriction/authorisation needs to take account of lead-times and product cycles that are application-specific. For some uses, legal limitations on substance use may be possible early, while more time is required for others given the lead-times and product cycles. So as to limit the cost and maximise benefits, decisions must take these factors into account.

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 70, paragraph 2

2. A final decision shall be taken in accordance with the procedure referred to in Article 130(3)**.**	2. A final decision shall be taken in accordance with the procedure referred to in Article 130(3)***, taking into account application-specific lead times and product cycles.***

Justification

Timing of restriction/authorisation needs to take account of lead-times and product cycles that are application-specific. For some uses, legal limitations on substance use may be possible early, while more time is required for others given the lead-times and product cycles. So as to limit the cost and maximise benefits, decisions must take these factors into account.

Amendment 227
Article 71 a (new)

	Article 71a
	Mission of the Agency
	The Agency shall be in charge of the overall management of the REACH process.

Justification

Entrusting the Agency with the full management of the REACH process will make REACH more workable and facilitate harmonised implementation in an independent transparent process.

Amendment 228
Article 71 b (new)

	Article 71b
	International responsibilities
	The Agency shall make all possible efforts to promote the international acceptability of REACH standards and equally shall take full account of existing standards established by other international institutions provided it is convinced of those standards' capacity to safeguard the environment and health.

Justification

It is important that producers and importers that have already registered under other international organisations standards have minimum bureaucratic and financial extra costs in order to comply with REACH. It is vital that EU producers are not susceptible to unfair competition from 'REACH-free' areas.

Amendment 229
Article 72, paragraph 1, point e

(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 divergences of opinions on draft decisions proposed by ***the Agency*** under Title VI and preparing the opinion of the Agency on proposals for identification of substances of very high concern to be subjected to the authorisation procedure under Title VII;

Justification

In line with amendments under Title VI.

Amendment 230
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.

Amendment 231
Article 73, paragraph 1 a (new)

1a. During the pre registration period the Agency should:

(a) let all the producers of similar substances know each other and get organised for registration purposes;

(b) make all the existing nonconfidential information on substances generally available (to be done by the Agency with the cooperation of existing institutions, Member States and industrial associations). This information should simplify the registration procedures of registrants (SMEs in particular);

(c) establish a schedule for the registration/evaluation of substances combining the degree of exposure with risk; substances should be classified by the producer/importer in three broad groups (high, medium and low risk) and priority should be given to the most dangerous substances (namely more than 1 000 tonnes and CMR 1&2). The classification proposed by the producer/importer can be rejected by the Agency.

(d) The final list of substances exempted from REACH should be published by the Agency by the end of this phase. All substances known at the moment to represent no risk to health and environment should be added to the list of exemptions, namely pulps used in paper manufacturing, recycling materials, certain ores, etc. The list of exempted substances should be periodically updated with new substances as knowledge increases.

Justification

It is important to reduce useless bureaucracy, foster agreements between companies/registering agents, reduce costs of registration and safeguard the interests of SMEs. (OSOR seems to be a positive contribution but the details of the proposal and the solutions to its confidentiality problems are still unknown.)

Amendment 232
Article 73, paragraph 2, subparagraph (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 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 performing a helpdesk function for economic operators, and in particular for SMEs***;

Justification

The Agency should also establish a helpdesk, in particular for SMEs.

Amendment 233
Article 73, paragraph (2), subparagraph (i) a (new)

	(ia) developing guidelines on the basis of product categories for the phasing-in of the obligations referred to in Article 6.

Justification

The Agency should take charge of the development of product-specific guidelines. In the free market economy, several best practice models already exist which can serve as a basis for the sector-specific guidelines. The guidelines should lay down how authorised chemicals are to be used in the various product categories. An overview of best practice models in the management of the supply chain should also be provided and it should be indicated how the authorised chemicals are to be notified.

Amendment 234
Article 73, paragraph 2, subparagraph (i) a (new)

	(ia) adopting a proactive stance with a view to ascertaining which developing countries export to the European Union products in which use is made of the first group of substances which have been identified as hazardous. These exporting developing countries should be approached without delay and above all must be guaranteed the same assistance as European countries. With developing countries too, alternatives

must be sought, they must be offered technical assistance and the knowledge available in the European Union must be shared with them.

Justification

The EU and its Member States must proactively approach developing countries which face difficulties and guarantee them the same assistance as European countries receive.

Amendment 235
Article 73, paragraph 2, subparagraph (i) a (new)

(ia) working with industrial sectors and other stakeholders to identify product categories for articles and the use of chemicals which fulfil the criteria referred to in REACH Article 54 (a-e) or have been identified in accordance with Article 54 (f) and developing product category based guidance notes for phasing in Article 6 obligations.

Justification

It is necessary that the Agency should take the lead in developing product-specific guidance and that such work should be based on a stakeholder approach. There are currently a number of good industry and individual company based practices which can provide a basis for the debate and development of the sector-specific guidance. The guidance notes should ideally identify how authorised chemicals are used in the product category, give an overview of best practice in supply chain management, explain how to notify the authorised chemicals and look at characteristics of consumer use and disposal.

Amendment 236
Article 73, paragraph 2 (i) b (new)

(ib) establishing and maintaining a centre of excellence in risk communication to consumers; providing a centralised and coordinated resource regarding information on the safe use of chemical substances and preparations; facilitating knowledge-sharing concerning best practice in the areas of hazard, risk and safe use 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 manage their risk safely and effectively when using a product containing chemicals.

Amendment 237
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 Chairman ***who is qualified to hold the office of judge in a Member State*** and two other members.

Justification

In view of the scope of the Board of Appeal's tasks, its Chairman must be a judge.

Amendment 238
Article 95

The structure and amount of the fees referred to in Article 93(1)(b) shall be set by the Management Board and shall be made public.	The structure and amount of the fees referred to in Article 93(1)(b) shall be set by the Management Board and shall be made public. ***The fees shall cover only the actual costs of registration.***

Justification

The fees should be reasonable and should correspond to the actual costs of registration. They should not be a tool for financing the exercise of public authority.

Amendment 239
Article 109

Scope	***deleted***
This Title shall apply to:	
(a) substances subject to registration by a manufacturer or importer;	
(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.

Justification

It is unnecessary to draw up a separate classification and labelling inventory, since classification and labelling will be part of the registration or core information process. This information will be contained in a database which the Agency will establish and maintain, under Article 73. An additional obligation to provide data for this inventory will place an unnecessary burden on producers and importers, without any gain of additional information.

Amendment 240
Article 110

Obligation to notify the Agency	***deleted***
1. Any importer or manufacturer, or group of importers or manufacturers, who place on the market a substance within the scope of Article 109, shall notify to the Agency the following information in order for it to be included in the inventory in accordance with Article 111, unless submitted as part of the registration:	
(a) the identity of the manufacturer or importer responsible for placing the substance(s) on the market;	
(b) the identity of the substance(s) as specified in part 2 of Annex IV;	
(c) the hazard classification of the substance(s), resulting from the application of Articles 4 and 6 of Directive 67/548/EEC;	
(d) the resulting hazard label for the substance(s), resulting from application of Articles 23, 24 and 25 of Directive 67/548/EEC;	
(e) specific concentration limits, where applicable, resulting from the application of Article 4(4) of Directive 67/548/EEC and	

Articles 4 to 7 of Directive 1999/45/EC.

2. In submitting this information, the manufacturer or importer shall use the format specified pursuant to Article 108.

3. Where the obligation under paragraph 1 results in different entries on the inventory for the same substance, the notifiers and registrants shall make every effort to come to an agreed entry to be included in the inventory.

4. The information listed in paragraph 1 shall be updated by the notifier(s) whenever:

(a) any new scientific or technical information is generated which results in a change to the classification and labelling of the substance;

(b) notifiers and registrants of differing entries for a single substance come to an agreed entry in accordance with paragraph 3.

Amendment 241
Article 111

deleted

The classification and labelling inventory

1. A classification and labelling inventory, listing the information referred to in Article 110(1), both for information notified under Article 110(1) as well as for information submitted as part of a registration, shall be established and maintained by the Agency in the form of a database. The non-confidential information in this database identified in Article 116(1) shall be publicly accessible. The Agency shall grant access to the other data on each substance in the inventory to the notifiers and registrants who have submitted information on that substance.

The Agency shall update the inventory when it receives updated information in accordance with Article 110(4).

2. In addition to the information referred to in paragraph 1, the Agency shall record the following information, where appropriate, against each entry:

(a) whether, in respect of the entry, there is a harmonised classification and labelling at Community level by inclusion in Annex I of Directive 67/548/EEC;

(b) whether it is an agreed entry of two or more notifiers or registrants;

(c) the relevant registration number(s), if available.

Amendment 242
Article 112

deleted

Harmonisation of classification and labelling

1. Harmonised classification and labelling at Community level shall, from the entry into force of this Regulation, only be added to Annex I of Directive 67/548/EEC for classification of a substance as carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, or as a respiratory sensitiser. To this end, Member State competent authorities may submit proposals to the Agency for harmonised classification and labelling in accordance with Annex XIV.
2. The Member State Committee shall formulate an opinion on the proposal, giving parties concerned the opportunity to comment. The Agency shall forward this opinion and any comments to the Commission, which shall take a decision in accordance with Article 4(3) of Directive 67/548/EEC.

Amendment 243
Article 113

deleted

Transitional arrangements

The obligations set out in Article 110 shall apply from the deadline established under Article 21(1).

Amendment 244
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 ***three*** 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 ***two years*** 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 245
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 ***three*** 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 Member States must report at much shorter intervals. This is the only way that deficiencies can be corrected at an early stage.

Amendment 246
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 ***three*** 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 ***two*** 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.

Amendment 247
Article 115 a (new)

	Article 115a
	Access to information for the general public
	1. Manufacturers of preparations for the general public or persons responsible for placing them on the market shall make available information that identifies risks associated with normal or reasonably foreseeable conditions of use, notably via on-pack labelling and complemented, when appropriate, by the use of other channels of communication, such as websites. This will allow the provision of more detailed safety and use information about chemical substances and preparations.
	2. Directives 1999/45/EC[1] and 1967/548/EEC shall be amended

accordingly.

3. A special 'REACH Compliant' mark shall be created in order to allow consumers the right of choice. This mark shall be attributable to those EU produced and imported goods that comply with all the REACH requirements.

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[1] OJ L 6, 12.1.1999, p. 3.

Justification

An appropriate and consistent communication system based on risk will provide consumers with the necessary information and advice to enable them to manage their risk safely and effectively when using a product containing chemicals. Information should be given in a comprehensive consumer-friendly method.

Amendment 248
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 249
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 250

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[1] are applicable***; _____ ***1 OJ L 200, 30.7.1999, p.1.***

Justification

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

Amendment 251
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[1], unless different provisions under Annex Ia of this Regulation or Article 15 of Directive 1999/45/EC[2] are applicable***; _____ ***1 OJ P 196, 16.8.1967, p.1.*** ***2 OJ L 200, 30.7.1999, p.1.***

Amendment 252
Article 116, paragraph 1, point f

(f) any derived no-effect level (Dnel) or predicted no-effect concentration (Pnec) established in accordance with Annex I;	***deleted***

Justification

The existing law does not provide for disclosure of Dnel values. Deriving these values is expensive and the information should not be made accessible to competitors without due consideration (Art. 115).

Amendment 253
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 254
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 255
Article 116, paragraph 2, point d

(d) links between a manufacturer or importer and his downstream users.	(d) links between a manufacturer or importer and his downstream users***, both upwards and downwards along the information chain and between all the actors in the chain***.

Justification

The proposal is not quite clear with regard to the duty of confidentiality between all actors in the information chain.

Amendment 256
Article 120, paragraph 1

The competent authorities of the Member States shall inform the general public about	***In accordance with the guidelines to be drawn up by the Agency, the*** competent

the risks arising from substances where this is considered necessary for the protection of human health or the environment.	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 257
Article 121

The competent authorities shall provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation, in addition to the operational guidance documents provided by the Agency under Article 73(2)(f).	The competent authorities shall provide advice to manufacturers, importers, downstream users and any other interested parties on their respective responsibilities and obligations under this Regulation, in addition to the operational guidance documents provided by the Agency under Article 73(2)(f). ***This shall include in particular, but not be limited to, advice to SMEs on how to meet their obligations under this Regulation.***

Justification

In particular SMEs may require special help so as to meet their obligations.

Amendment 258
Article 128, new second paragraph

	No later than 24 months after the entry into force of this Regulation, a section shall be inserted at the beginning of Annex II which lays down objective criteria and the list of exempted substances which shall be periodically updated for the exemption of substances and/or groups of substances.

Justification

The current Annex II is based on 'historical precedent'. As such it is inconsistent and builds on

unclear criteria, leading to absurdities where one of two similar substances is excluded while the other is not (i.e. sucrose and fructose). The Commission should be given a deadline within which to develop clear objective criteria for granting the exemptions contained in Annex II, so that a logical and comprehensive list of exempted substances can be developed.

Amendment 259
Article 128, new second paragraph

	Revision of Annex II
	(i) During pre-registration, the Agency shall add those substances which fall under the definition.
	(ii) After evaluation, the Agency shall add those substances which it deems to constitute no risk or low risk of causing ill-health or negative environmental effects.
	(iii) Undertakings may apply for an exemption from registration, with reference to a traditional use and naturally occurring substances and mixtures or compounds thereof.

Justification

There is currently no definition for the substances listed in Annex II, e.g. water and ascorbic acid. Adding a definition clarifies the text and also makes revision possible. Although we add substances to Annex II during the legislative process, we are convinced that it will not be exhaustive. We would therefore like a revision at an early stage but also on a rolling basis during the process as we acquire more knowledge. Without our amendments, several substances will have to be registered for a long time in the future despite the fact that the Agency knows that those substances do not constitute a risk.

Amendment 260
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[1],*** 91/157/EEC, 93/67/EEC, 93/105/EEC and 2000/21/EC***, 2002/95/EC[2] and 2004/37/EC[3]*** and Regulations (EEC) No 793/93 and (EC) No 1488/94 are repealed.
	_____
	1 OJ L 076, 22.3.1991, p.35.
	2 OJ L 037, 13.2.2003, p.19.
	3 OJ L 158, 30.4.2004, p.50.

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 261
Article 135 a (new)

Article 135a
Amendment of Directive 1998/24/EC

The following words are added to Article 1(2) of Directive 98/24/EC[1]:

'Requirements under this directive shall not apply in the event of obligations under Regulation (EC) No xxx (REACH Regulation).'

1 OJ L 131, 5.5.1998, p.11.

Justification

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

Amendment 262
Article 135 b (new)

Article 135b.

Amendment of Directive 2004/37/EC

An additional paragraph 5 is added to Article 1 of Directive 2004/37/EC[1], as follows:

'Requirements under this directive shall not apply in the event of obligations under Regulation (EC) No xxx (REACH Regulation).'

1 OJ L 158, 30.4.2004, p.50.

Justification

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

Amendment 263
Article 135 c (new)

Article 135c

Amendment of Directive 89/106/EEC

The following words are added to Article 1(1) of Directive 89/106/EEC[1]:

'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.'

1 OJ L 40, 11.2.1989, p.12.

Justification

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

Amendment 264
Article 135 d (new)

Article 135d

Amendment of Directive 2000/53/EC

Article 4(2) and Annex II of Directive 2000/53/EC[1] are deleted.

1 OJ L 269, 21.10.2000, p.34.

Justification

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

Amendment 265
Annex I, Heading 5

5.1.1. Exposure scenarios shall be developed for manufacture in the Community, manufacturer's and importer's own use, and	5.1.1. Exposure 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:	all identified uses ***as referred to in Article 3 (25).*** 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 ***can be categorised in accordance with the definition laid down in Article 3 (29a) and*** 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:

Justification

The use and exposure categories are so designed as to make it possible to describe all types of identified uses by combining relevant constituent elements. They combine specific exposure situations and describe all conditions that determine exposure.

Amendment 266
Annex I, Heading 5.1.1, indent 3

– the risk management measures implemented by the manufacturer ***or*** importer to reduce or avoid exposure of humans (including workers and consumers) and the environment to the substance;	– the risk management measures implemented by the manufacturer***, importer and/or downstream user*** to reduce or avoid exposure of humans (including workers and consumers) and the environment to the substance;

Justification

Downstream users already apply risk management measures. These need to be considered in the development of exposure scenarios where appropriate and in the overall risk management measures recommended by the manufacturer and importer of substances.

Amendment 267
Annex I, Heading 5.2.5 a (new)

	5.2.5a Validated exposure estimations can be facilitated by the use of specialised IT

tools including sector-specific ones where they are available.

Justification

In order to help SMEs fulfil their obligations, specific and specialised IT Tools to perform an exposure assessment either exist or can be developed, including sector-specific ones.

Amendment 268
Annex I, Heading 7, Part A, paragraph -1

-1. DESCRIPTION OF THE USE AND EXPOSURE CATEGORIES (UEC) COVERED

Justification

UEC are the main instrument for the structured transfer of information on risk management measures, exposure target values (e.g. DNEL, PNEC) and conditions of use along the supply chain. They support the actors in the supply chain in their own risk assessment and in the establishment of a safety data sheet for the subsequent actors in the supply chain.

Amendment 269
Annex Ia, Heading 3.3 a (new)

3.3a. For preparations not fulfilling the requirements of 3.2 and 3.3 and for which the PNEC of the used substances is lower than 500 µg/litre, the quantity, biodegradation (eliminability) and logPOW shall be communicated to the downstream user in accordance with the requirements of Articles 34 and 35.

Justification

A substance may be critical in use, if the downstream user has a 'weak' pre-flooder and the PNEC of the substance is lower than 500 µg/l. These are relevant properties of the substances that must be communicated to downstream users if they have to perform an exposure assessment and a chemical safety report in accordance with Articles 34 and 35.

Amendment 270
Annex Ia, Heading 12.1, new paragraph to follow first paragraph

For preparations, this information shall be given for each relevant substance in a preparation and for the preparation itself. If, for the preparation itself, this information cannot be given as a concrete value but only as a range of data, the ecotoxicity information of the relevant substances, according to the rules under headings 2 and 3 of this annex, in the preparation shall be given.

Justification

In some cases, the information requested is not preparation-specific but substance-specific and vice versa. It should therefore be given where it is required for the substances and preparations by the safety datasheet in accordance with headings 2 and 3 of Annex 1a.

Amendment 271
Annex II, new introductory paragraph

Definition

This Annex contains substances which are exempt from registration. The Annex covers naturally occurring substances and mixtures or compounds which mainly consist thereof, in respect of which there is lengthy experience unequivocally indicating the absence of risk or very low risks of causing ill-health or negative environmental effects.

Justification

There is currently no definition for the substances listed in Annex II, e.g. water and ascorbic acid. Adding a definition clarifies the text and also makes revision possible.

Although we add substances to Annex II during the legislative process, we are convinced that it will not be exhaustive. We would therefore like a revision at an early stage but also on a rolling basis during the process as we acquire more knowledge. Without our amendments, several substances will have to be registered for a considerably long time in the future despite the fact that the Agency knows that those substances do not constitute a risk.

Amendment 272
Annex II

EINECS no	Name/Group	CAS no	EINECS no	Name/Group	CAS no
			231-096-4	***Iron***	***7439-89-6***

Justification

Iron has been used for thousands of years without any evidence that iron presents risks to human health or the environment. Because iron is a high tonnage material, it is likely to have 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 273
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, substances occurring in nature ***and materials derived from them by mineralogical processes (as defined in Council Directive 2003/96/EC)[1] or physical transformation processes;***
	[1] OJ L 283, 31.10.2003, p. 51.

Justification

If classified as dangerous according to 67/548, the registration requirement is disproportionate in respect of minerals, ores and substances occurring in nature. Potential risks arising from minerals and ores are addressed under the IPPC Directive and existing EU workplace legislation. Mineralogical and physical transformation processes of minerals and ores do not change the chemical composition. The materials derived from these processes are other mineral-based materials and should be exempted from registration.

Amendment 274
Annex III, paragraph 8a (new)

8a. Pulps used in paper manufacturing.

Justification

Pulps used for paper manufacturing are chemically inactive and as such completely harmless to human health and the environment. They should not be subject to registration under REACH.

Amendment 275
Annex III paragraph 9

Natural gas, crude oil, coal	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. All transport is by pipeline and the gases are never encountered by the general public. 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 and should therefore be exempted from registration. 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. They should therefore be treated equally with the natural energy sources and, hence, be exempt from the obligation to register.

Amendment 276
Annex V point 6 - Toxicological Information, column 1, point 6, subpoint -1 (new)

	-1. Acute toxicity
	- by oral route
	- by inhalation
	- by dermal route

Justification

Data on acute toxicity constitutes THE basic toxicological information and should hence be included even for the low-volume substances. It plays a central role for the evaluation of worker safety requirements, and furthermore it is relatively inexpensive at approx. €1800 per substance.

Amendment 277
Annex V point 7 - Ecotoxicological Information, column 1, subpoint 1.1 a (new)

	7.1.1a. Growth inhibition study on algae

Justification

The proposal only makes daphnia toxicity tests compulsory. However, this test does not allow even a rudimentary environmental assessment, as it provides only for studying the impacts of a substance on animal organisms. For assessing the impact on plant organisms as well, the inclusion of an algae growth inhibition test is indispensable. The cost of the test is approx. €5000 per substance.

Amendment 278
Annex V, point 7 a (new)- Biodegradability

7 a. Biodegradability

7.1 Ready biodegradability

Justification

Biodegradability is indispensable for ecotoxicological assessment. Without it the impact of a substance on the environment cannot be assessed even if a lot of other information is available. It is especially important for determining whether a substance fulfils the criteria of Annex XII, i.e. can be said to belong to the PBT/vPvB group. The cost of such a test (€4840 per substance according to the German Government) should not be prohibitive to its inclusion in the basic data requirements.

PROCEDURE

Title	Proposal for a regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}
References	COM(2003)0644 – C5-0530/2003 – 2003/0256(COD)
Committee responsible	ENVI
Committee asked for its opinion Date announced in plenary	INTA 16.09.2004
Draftsperson Date appointed	Godelieve Quisthoudt-Rowohl 28.7.2004
Discussed in committee	31.8.2004 3.2.2005 14.6.2005 29.8.2005
Date amendments adopted	12.9.2005
Result of final vote	for: 24 against: 4 abstentions: 0
Members present for the final vote	Kader Arif, Enrique Barón Crespo, Jean-Louis Bourlanges, Daniel Caspary, Françoise Castex, Giulietto Chiesa, Christofer Fjellner, Glyn Ford, Béla Glattfelder, Jacky Henin, Erika Mann, Helmuth Markov, David Martin, Javier Moreno Sánchez, Georgios Papastamkos, Godelieve Quisthoudt-Rowohl, Tokia Saïfi, Peter Šťastný, Robert Sturdy, Johan Van Hecke, Zbigniew Zaleski
Substitutes present for the final vote	Margrietus van den Berg, Reimer Böge, Jorgo Chatzimarkakis, Elisa Ferreira, Zuzana Roithová
Substitutes under Rule 178(2) present for the final vote	Marie Anne Isler Béguin, Gérard Onesta
Comments	