EUROPEAN PARLIAMENT

1999 *2004*

Committee on the Environment, Public Health and Consumer Policy

PROVISIONAL
2003/0256(COD)

6 January 2004

***I
DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} (COM(2003) 644 – C5-0530/2003 – 2003/0256(COD))

Committee on the Environment, Public Health and Consumer Policy

Rapporteur: Guido Sacconi

Symbols for procedures

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

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

Amendments to a legislative text

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

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PROCEDURAL PAGE

By letter of 31 October 2003 the Commission submitted to Parliament, pursuant to Article 251(2) and Article 95 of the EC Treaty, the proposal for a regulation of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants} (COM(2003) 644 – 2003/0256(COD)).

At the sitting of 3 December 2003 the President of Parliament announced that he had referred the proposal to the Committee on the Environment, Public Health and Consumer Policy as the committee responsible and to the Committee on Budgets, the Committee on Economic and Monetary Affairs, the Committee on Legal Affairs and the Internal Market, the Committee on Industry, External Trade, Research and Energy and the Committee on Employment and Social Affairs for their opinions (C5-0530/2003).

The Committee on the Environment, Public Health and Consumer Policy had appointed Guido Sacconi rapporteur at its meeting of 16 June 2003.

It considered the Commission proposal and draft report at its meeting(s) of ... .

At the latter/last meeting it adopted the draft legislative resolution by ... votes to ..., with ... abstention(s)/unanimously.

The following were present for the vote: ... (chair(wo)man/acting chair(wo)man), ... (vice-chair(wo)man), ... (vice-chair(wo)man), Guido Sacconi (rapporteur), ..., ... (for ...), ... (for ... pursuant to Rule 153(2)), ... and ... .

(The opinion(s) of the Committee on ... (and the Committee on ...) is (are) attached.) (The Committee on ... decided on ... not to deliver an opinion.)

The report was tabled on ... .

DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}
(COM(2003) 644 – C5-0530/2003 – 2003/0256(COD))

(Codecision procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to the European Parliament and to the Council (COM(2003) 644)[1],

– having regard to Article 251(2) and Article 95 of the EC Treaty, pursuant to which the proposal was submitted by the Commission (C5-0530/2003),

– having regard to Rule 67 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Consumer Policy and the opinions of the Committee on Budgets, the Committee on Economic and Monetary Affairs, the Committee on Legal Affairs and the Internal Market, the Committee on Industry, External Trade, Research and Energy and the Committee on Employment and Social Affairs (A5-0000/2003),

1. Approves the Commission proposal as amended;

2. Calls on the Commission to refer the matter to Parliament again if it intends to amend the proposal substantially or replace it with another text;

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

Text proposed by the Commission	Amendments by Parliament
	Amendment 1 Recital 3 a (new)
	(3a) Pursuant to the action plan adopted on 4 September 2002 at the Johannesburg World Summit on sustainable development, chemicals must, by 2020, be produced and used in a way which is not damaging to human health and the environment.

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

Justification

It should be pointed out that the objective of eventually producing and using only chemicals which are not harmful to human health and the environment is a commitment to be honoured not just by the European Union but by the world as a whole.

Amendment 2
Recital 7

(7) An important objective of the new system to be established by this Regulation is to ***encourage the substitution of*** dangerous substances by less dangerous substances or technologies where suitable alternatives are available. This Regulation does not affect the application of Directives on worker protection, especially Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) under which employers are required to eliminate dangerous substances, wherever technically possible, or to substitute dangerous substances with less dangerous substances.	(7) An important objective of the new system to be established by this Regulation is to ***ensure that*** dangerous substances ***are substituted*** by less dangerous substances or technologies where suitable alternatives are available. This Regulation does not affect the application of Directives on worker protection, especially Council Directive 90/394/EEC of 28 June 1990 on the protection of workers from the risks related to exposure to carcinogens at work (Sixth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) under which employers are required to eliminate dangerous substances, wherever technically possible, or to substitute dangerous substances with less dangerous substances.

Justification

Self-explanatory.

Amendment 3
Recital 8 a (new)

	(8a) Producers, importers and downstream users of a substance in its basic form or as a component of a preparation or of an article are required to manufacture, import or use that substance (or place it on the market) in such a way as to ensure that, under reasonably foreseeable conditions, no damage is caused to human health or to the environment.

Justification

This amendment introduces the general principle of the duty of care. Since REACH does not cover all uses of chemicals, it is important from the point of view of protecting human health and the environment that a general duty of care be established as regards the production and the use of substances. Such a principle would merely codify the voluntary undertakings which the industry is promoting (e.g. the Responsible Care Programme).

Amendment 4
Recital 12

(12) The authorisation provisions provide for authorisations for the placing on the market and use of substances of very high concern to be granted by the Commission ***if*** the risks arising from their use are adequately controlled ***or the use can be justified for socio-economic reasons***.	(12) The authorisation provisions provide for authorisations for the placing on the market and use of substances of very high concern to be granted by the Commission ***where no valid alternatives exist, where the use of such substances can be justified on socio-economic grounds and where*** the risks arising from their use are adequately controlled.

Justification

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

Amendment 5
Recital 16

(16) Experience has shown that it is inappropriate to require Member States to assess the risks of all chemical substances. This responsibility should therefore be given, in the first place, to the enterprises that manufacture or import substances, but only when they do so in quantities exceeding a certain volume, to enable them to carry the associated burden. Those enterprises should take the necessary risk management measures in accordance with their assessment of the risks of their substances.	(16) Experience has shown that it is inappropriate to require Member States to assess the risks of all chemical substances. This responsibility should therefore be given, in the first place, to the enterprises that manufacture or import substances, but only when they do so in quantities exceeding a certain volume, to enable them to carry the associated burden. Those enterprises should take the necessary risk management measures in accordance with their assessment of the risks of their substances. ***This includes the duty to describe, document and notify in an appropriate, transparent fashion the risks stemming from the production, use and sale of each substance. Producers and downstream users will select a substance***

	for production and use on the basis of the safest substances available.

Justification

This introduces the principle of the 'duty of care'.

Amendment 6
Recital 20

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

Justification

This introduces the requirement to register substances contained in articles, whether or not those substances are intended to be released into the atmosphere.

Amendment 7
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 provide an indication of the potential for exposure of man and the environment to the substances, and should be described in detail.	(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. ***Such a criterion could be subject to review by the Commission and could possibly be revised or incorporated with other qualitative criteria such as degree of intrinsic hazardousness, use and exposure.***

Justification

This allows the Commission the possibility of revising the prioritisation criteria for the registration of substances.

Amendment 8
Recital 49

(49) The Agency should also be empowered to require further information from manufacturers, importers or downstream users on substances suspected of posing a risk to health or the environment, including by reason of their presence on the internal market in high volumes, on the basis of evaluations performed by Member State competent authorities. Member States should be made to plan and provide resources to this end, through the establishment of rolling plans. If a risk equivalent to the level of concern arising from the use of substances subject to authorisation arises from the use of isolated intermediates on site, Member States should also be allowed to require further information, when justified.	(49) The Agency should also be empowered to require further information from manufacturers, importers or downstream users on substances suspected of posing a risk to health or the environment, including by reason of their presence on the internal market in high volumes, on the basis of evaluations performed by Member State competent authorities. Member States should be made to plan and provide resources to this end, through the establishment of rolling plans ***developed on the basis of a list (drawn up by the Agency) of substances earmarked for priority evaluation***. If a risk equivalent to the level of concern arising from the use of substances subject to authorisation arises from the use of isolated intermediates on site, Member States should also be allowed to require further information, when justified.

Justification

The Agency is responsible for drawing up the priority list of substances to be evaluated by the Member States.

Amendment 9
Recital 50

(50) ***Collective*** agreement ***among Member State authorities on their draft decisions*** provides the basis for an efficient system that respects the principle of subsidiarity, while maintaining the internal market. If ***one or more Member States or*** the Agency ***do*** not agree to a draft decision, it should	(50) ***Unanimous*** agreement ***within the Agency's Member State Committee on the draft decision*** provides the basis for an efficient system that respects the principle of subsidiarity, while maintaining the internal market. If the Agency ***does*** not agree to a draft decision, it should be made

be made subject to a centralised procedure. The Agency should take the decisions following from the application of these procedures.	subject to a centralised procedure. The Agency should take the decisions following from the application of these procedures.

Justification

Linked to Amendment 8.

Amendment 10
Recital 52

(52) To ensure a sufficiently high level of protection for human health and the environment, substances with properties of very high concern should be treated in a precautionary manner which requires enterprises using them to demonstrate to the granting authority that ***the risks are adequately controlled***. ***If this is not the case, uses may still be authorised if enterprises show that*** the benefits to society from the use of the substance outweigh the risks connected with its use ***and*** there are no suitable alternative substances or technologies. The granting authority should then verify that these requirements are met through an authorisation procedure on the basis of applications by enterprises. Since authorisations should ensure a high level of protection throughout the internal market, it is appropriate that the Commission should be the granting authority.	(52) To ensure a sufficiently high level of protection for human health and the environment, substances with properties of very high concern should be treated in a precautionary manner which requires enterprises using them to demonstrate to the granting authority that the benefits to society from the use of the substance outweigh the risks connected with its use***, that*** there are no suitable alternative substances or technologies ***and that the risks are adequately controlled***. The granting authority should then verify that these requirements are met through an authorisation procedure on the basis of applications by enterprises. Since authorisations should ensure a high level of protection throughout the internal market, it is appropriate that the Commission should be the granting authority.

Justification

'Adequate control' of a substance is a criterion of secondary importance to the granting of authorisation.

Amendment 11
Recital 55

(55) The Agency should ***provide advice on*** the prioritisation of substances to be made subject to the authorisation procedure, to ensure that decisions reflect the needs of society as well as scientific knowledge and developments.	(55) The Agency should ***lay down*** the prioritisation of substances to be made subject to the authorisation procedure, to ensure that decisions reflect the needs of society as well as scientific knowledge and developments.

Justification

The Agency is responsible for drawing up the priority list of substances to be evaluated by the Member States.

Amendment 12
Recital 71

(71) In the interests of efficiency, the staff of the Agency ***Secretariat*** should perform essentially technical-administrative and scientific tasks without calling on the scientific and technical resources of the Member States; the Executive Director should ensure the efficient execution of the Agency's tasks in an independent manner. To ensure that the Agency fulfils its role, the composition of the Management Board should be designed to secure the highest standard of competence and a broad range of relevant expertise in chemicals safety or the regulation of chemicals.	(71) In the interests of efficiency, the staff of the Agency should perform essentially technical-administrative and scientific tasks without calling on the scientific and technical resources of the Member States; the Executive Director should ensure the efficient execution of the Agency's tasks in an independent manner. To ensure that the Agency fulfils its role, the composition of the Management Board should be designed to secure the highest standard of competence and a broad range of relevant expertise in chemicals safety or the regulation of chemicals.

Justification

Deletion of superfluous text.

Amendment 13
Recital 91 a (new)

	(91a) The Commission will consider the possibility of submitting a proposal with a view to creating a European mark designed to identify and promote articles which, at each stage of the production

	process, have been produced in compliance with the requirements stemming from this Regulation.

Justification

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

Amendment 14
Recital 100

(100) It is appropriate for the provisions of this Regulation to enter into force in a staggered way to smooth the transition to the new system; moreover, a gradual entry into force of the provisions should allow all parties involved, authorities, enterprises as well as stakeholders, to focus resources in the preparation for new duties at the right times.	(100) It is appropriate for the provisions of this Regulation to enter into force in a staggered way to smooth the transition to the new system; moreover, a gradual entry into force of the provisions should allow all parties involved, authorities, enterprises as well as stakeholders, to focus resources in the preparation for new duties at the right times***, including through the conclusion of voluntary Commission-coordinated agreements between industry and other interested parties***.

Justification

The conclusion of voluntary agreements is intended as a means of incorporation into this legislation.

Amendment 15
TITLE I - GENERAL ISSUES
Chapter 2 - Definitions
Article 3, paragraph 1

1. *Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but	1. *Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used ***or***

excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;	***naturally present and extracted along with the substance***, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;

Justification

Self-explanatory.

Amendment 16
TITLE I - GENERAL ISSUES
Chapter 2 - Definitions
Article 3, paragraph 14 a (new)

	14a. **Chemically unmodified substance** ***means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process - for example, where a substance has been chemically treated for the purpose of removing impurities.***

Justification

Self-explanatory.

Amendment 17
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 2 - General obligation to register and information requirements
Article 6, paragraph 1, letter b

(b) the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC;	(b) the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC ***or is PBT or VPVB***;

Justification

Self-explanatory.

Amendment 18
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 2 - General obligation to register and information requirements
Article 6, paragraph 1, letter c

(c) the substance is intended to be released under normal and reasonably foreseeable conditions of use.	(c) the substance is intended to ***(or will probably)*** be released under normal and reasonably foreseeable conditions of use ***(even if such release is not an intended function of the article) and the quantity of the substance released may have a harmful effect on human health or on the environment***.

Justification

It is considered more practical for a single registration system to be set up and for the notification system therefore to be abolished.

Amendment 19
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 2 - General obligation to register and information requirements
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

Linked to Amendment 18.

Amendment 20
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 2 - General obligation to register and information requirements
Article 6, paragraph 3

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 Amendment 18.

Amendment 21
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 2 - General obligation to register and information requirements
Article 6, paragraph 4

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

Justification

Linked to Amendment 18.

Amendment 22
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 2 - General obligation to register and information requirements
Article 6, paragraph 5

5. Paragraph***s*** 1 ***to 4*** shall not apply to substances that have already been registered for that use by an actor up the supply chain.	5. Paragraph 1 shall not apply to substances that have already been registered for that use by an actor up the supply chain.

Justification

Linked to Amendment 18.

Amendment 23
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 2 - General obligation to register and information requirements
Article 6, paragraph 6

6. Paragraph***s*** 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(3).

Justification

Linked to Amendment 18.

Amendment 24
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 2 - General obligation to register and information requirements
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 paragraphs 1 to ***3*** shall be adopted in accordance with the procedure referred to in Article 130(3).

Justification

Linked to Amendment 18.

Amendment 25
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 2 - General obligation to register and information requirements
Article 13, paragraph 4, second subparagraph

The exposure assessment and the risk characterisation shall address all identified uses of the manufacturer or importer	***Deleted***

Justification

The burden of obligations on downstream users should be lightened by requiring suppliers to incorporate a range of intended uses into their safety report. Linked to amendment 31.

Amendment 26
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 5 - Common provisions for all registrations
Article 19, paragraph 1, third subparagraph

In the case of registrations of phase-in substances submitted within 2 months	In the case of registrations of phase-in substances submitted within 2 months

before the relevant deadline of Article 21 as referred to in Article 18(2), a registrant may continue the manufacture or import of the substance for 3 months from that deadline or until rejection by the Agency, whichever is the earlier.	before the relevant deadline of Article 21 as referred to in Article 18(2), a registrant may continue the manufacture or import of the substance for 3 months from that deadline or until ***any*** rejection by the Agency, whichever is the earlier.

Justification

Self-explanatory.

Amendment 27
TITLE II - REGISTRATION OF SUBSTANCES
Chapter 6 - Transitional provisions applicable to phase-in substances and notified substances
Article 21, paragraph 1, letter a

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

Justification

With a view to providing adequate protection for human health and the environment, the registration system should right from the start include all substances which meet the authorisation criteria.

Amendment 28
TITLE III - DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING
Chapter 3 - Rules for phase-in substances
Article 26, paragraph 2, letter a

(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;	(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 ***and substances classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC, or***

	subject to the Article 54 authorisation criteria, and produced in the Community or imported in quantities reaching 1 tonne or more per year;

Justification

A link with Article 21 must be established as regards the deadlines for existing substances.

Amendment 29
TITLE III - DATA SHARING AND AVOIDANCE OF UNNECESSARY TESTING
Chapter 3 - Rules for phase-in substances
Article 27, paragraph 1 a (new)

	1a. Downstream users shall have access to SIEF information on the uses of substances.

Justification

Transparency is required at every stage of the process.

Amendment 30
TITLE IV - INFORMATION IN THE SUPPLY CHAIN
Article 29, paragraphs 1 and 2

1. Where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC, the person responsible for placing that substance or preparation on the market, whether the manufacturer, importer, downstream user or distributor, shall supply the recipient, who is a downstream user or distributor of the substance or preparation, with a safety data sheet compiled in accordance with Annex Ia.	1. Where a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC, the person responsible for placing that substance or preparation on the market, whether the manufacturer, importer, downstream user or distributor, shall supply the recipient, who is a downstream user or distributor of the substance or preparation, with a safety data sheet ***relating to the substance or the preparation and*** compiled in accordance with Annex Ia.
2. Any actor in the supply chain who is required, under Articles 13 or 34, to carry out a chemical safety assessment as part of his registration for a substance shall ensure that the information in the safety data sheet is consistent with the information in this	2. Any actor in the supply chain who is required, under Articles ***6,*** 13 or 34, to carry out a chemical safety assessment as part of his registration for a substance shall ensure that the information in the safety data sheet is consistent with the

assessment.	information in this assessment.

Justification

Producers, importers and downstream users must be able to choose whether or not to draw up their own safety data sheet for the substance or preparation concerned.

Producers and importers of articles are also required to register the substances contained in those articles.

Amendment 31
TITLE IV - INFORMATION IN THE SUPPLY CHAIN
Article 29, paragraph 7

7. ***For identified uses,*** a downstream user shall use appropriate information from the safety data sheet supplied to him.	7. A downstream user shall use appropriate information from the safety data sheet supplied to him ***and shall check that his exposure conditions correspond to the scenarios described and recorded on the safety sheet***.

Justification

The burden of obligations on downstream users should be lightened by requiring suppliers to incorporate a range of intended uses into their safety report.

Amendment 32
TITLE IV - INFORMATION IN THE SUPPLY CHAIN
Article 32

Workers ***and*** their representatives shall be granted access by their employer to the information provided in accordance with Article 29 and 30 in relation to substances they use or may be exposed to in the course of their work.	Workers***,*** their representatives ***and consumers*** shall be granted access by their employer ***or supplier*** to the information provided in accordance with Article 29 and 30 in relation to substances they use or may be exposed to in the course of their work.

Justification

Consumer-protection organisations also have a right of access to information.

Amendment 33
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation

Article 43 a

Criteria for substance evaluation	***Evaluation criteria and list of the priority substances for evaluation***
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.***	***1.*** In order to provide a harmonised approach, the Agency shall develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria for evaluation shall include consideration of hazard data, exposure data and tonnage bands. The Agency shall take a decision on the criteria for the prioritisation of substances for further evaluation.

Justification

In order to simplify the procedure and to prevent disparities from arising amongst the Member States owing to the use of a decentralised procedure, it is proposed that the Agency be given the task of compiling the list of priority substances for evaluation and that the Agency be given a greater role in the decision-making procedure relating to substance evaluation.

Amendment 34
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
Article 43 a, paragraph 1 a (new)

	1a. The Agency shall use such criteria for the purpose of compiling a list of priority substances for evaluation. The Agency shall adopt that list on the basis of an opinion drawn up by the Member State Committee. Substances shall be included on the list if there are grounds for considering (either on the basis of a dossier evaluation carried out by one of the competent authorities referred to in Article 38 or on the basis of any other appropriate source, including information contained in the registration dossiers) that a given substance constitutes a risk to health or to the environment, in particular on account of one of the following circumstances:

(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

Linked to amendment 33.

Amendment 35
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
Article 43 a, paragraph 1 b (new)

1b. The Agency shall publish the list of priority substances for evaluation on its own website.

Justification

Self-explanatory.

Amendment 36
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
Article 43 a bis, 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 environment, in particular on the basis of***	1. ***The Member States shall draw up their own rolling plans.*** A Member State shall include a substance ***from the list referred to in Article 43a(1a) in its own*** rolling plan, with the aim of becoming competent authority for the purposes of Articles 45 and 46.

either of the following:

(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

Linked to Amendment 33.

Amendment 37
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
Article 43 a bis, paragraph 2

2. A rolling plan as referred to in paragraph 1 shall cover a period of three years, updated annually, and shall specify the substances which the Member State is planning to evaluate each year. The Member State shall submit the rolling plan to the Agency ***and the other Member States*** by 28 February each year. The Agency may make comments and Member States may send their comments to the Agency or express their interest in evaluating a substance by 31 March of each year.	2. A rolling plan as referred to in 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 by 28 February each year. ***The Agency shall publish the rolling plans on its website.*** 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.

Justification

Self-explanatory.

Amendment 38
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
Article 43 a bis, paragraph 6

6. The competent authority identified in accordance with paragraphs ***1*** to 4 shall evaluate all substances on its rolling plan in accordance with this Chapter.	6. The competent authority identified in accordance with paragraphs ***2*** to 4 shall evaluate all substances on its rolling plan in accordance with this Chapter.

Justification

Linked to Amendment 36.

Amendment 39
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
Article 43 a bis, paragraph 6 a (new)

	6a. A Member State may notify the Agency at any time of a new substance, whenever it is in possession of information which suggests that there is a danger to the environment and to human health. The Agency shall add that substance to the list of substances to be evaluated using the prioritisation criteria laid down in Article 43a.

Justification

The Agency should take into account all relevant information concerning the hazardousness of a substance.

Amendment 40
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
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 43***a bis (1)***, including, if appropriate, information not required in Annexes V to VIII, it shall prepare a draft decision, stating reasons, requiring the registrant(s) to submit the further information. The decision shall be taken in accordance with the procedure laid down in Articles 48 and 49.	1. If the ***Agency*** considers that further information is required for the purposes of clarifying the suspicion, referred to in Article 43***(1a)***, 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.

Justification

Linked to Amendment 33.

Amendment 41
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
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.	***Deleted***

Justification

The significance of this paragraph as regards the procedure for obtaining additional information is not clear.

Amendment 42
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
Article 45, paragraph 2

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

Justification

Linked to Amendment 33.

Amendment 43
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 3 - Substance evaluation
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.

Justification

Linked to Amendment 33.

Amendment 44
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 5 - Common provisions
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 competent authority shall communicate any draft decision under Articles 39 ***or*** 40 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.

Justification

Linked to Amendment 33.

Amendment 45
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 5 - Common provisions
Article 48, paragraph 3 a (new)

	3a. The provisions contained in paragraphs 1 to 3 shall apply mutatis mutandis in the case of draft decisions taken by the Agency pursuant to Article 44.

Justification

Linked to Amendment 33.

Amendment 46

TITLE VI - EVALUATION OF SUBSTANCES
Chapter 5 - Common provisions
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 competent authority of a Member State shall notify its draft decision in accordance with Article 39 ***or*** 40 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.

Justification

Linked to Amendment 33.

Amendment 47
TITLE VI - EVALUATION OF SUBSTANCES
Chapter 5 - Common provisions
Article 49 a (new)

	In the case of draft decisions taken by the Agency pursuant to Article 44, the Agency shall submit a draft decision to the Member State Committee, specifying the way in which it has taken account of any observations submitted by the registrant or by the downstream user.
	The provisions of Article 49(5) to (8) shall apply to this article.

Justification

Linked to Amendment 33.

Amendment 48
TITLE VII - AUTHORISATION
Chapter 1 - Authorisation requirement
Article 52

The aim of this Title is to ensure the good functioning of the internal market while assuring that ***the risks from*** substances of	The aim of this Title is to ensure the good functioning of the internal market while assuring that substances of very high

very high concern are ***properly controlled or that these substances are*** replaced by suitable alternative substances or technologies.	concern are replaced by suitable alternative substances or technologies ***where such are available***.

Justification

The purpose of this is to reverse the order proposed by the Commission and, therefore, to reduce the importance of the concept of 'adequate controls'. A clearer link with the principle of substitution should also be established.

Amendment 49
TITLE VII - AUTHORISATION
Chapter 1 - Authorisation requirement
Article 55, paragraph 4, introductory paragraph

4. Before the Agency sends its recommendation to the Commission it shall make it publicly available on its website, clearly indicating the date of publication. The Agency ***shall*** invite all interested parties to submit comments within three months of the date of publication, in particular on the following:	4. Before the Agency sends its recommendation to the Commission it shall make it publicly available on its website, clearly indicating the date of publication. The Agency ***may*** invite all interested parties to submit comments within three months of the date of publication, in particular on the following:

Justification

Self-explanatory.

Amendment 50
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 57, paragraph 2

2. An authorisation shall be granted if ***the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII is adequately controlled in accordance with Annex I, section 6, and as documented in the applicant's chemical safety report.***	2. An authorisation shall be granted ***only*** if:

The Commission shall not consider the following:	
(a) risks to human health ***and*** the environment ***of emissions of the substance from an installation for which a permit was granted in accordance with Council Directive 96/61/EC***;	(a) ***it is demonstrated that the social and economic advantages outweigh the*** risks to human health ***or*** the environment ***which arise from the use of the substance, and***
(b) ***risks to and via the aquatic environment of discharges of the substance from a point source governed by the requirement for prior regulation referred to in Article 11 (3) and legislation adopted under Article 16 of Directive 2000/60/EC of the European Parliament and of the Council;***	(b) ***suitable alternative substances or technologies do not exist, and***
(c) ***risks*** to human health arising from the use of a substance ***in a medical device regulated by Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC of the European Parliament and of the Council.***	(c) ***the risk*** to human health ***or the environment from*** the use of a substance ***arising from the intrinsic properties specified in Annex XIII is adequately controlled in accordance with Annex I, section 6, and as documented in the applicant's chemical safety record.***

Justification

Linked to Amendment 48.

Amendment 51
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 57, paragraph 3, introductory paragraph

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

Justification

Linked to Amendment 48.

Amendment 52
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 57, paragraph 3 a (new)

3a. In granting authorisation pursuant to paragraph 2 the Commission shall not consider the following:

(a) risks to human health and the environment of emissions of the substance from an installation for which a permit was granted in accordance with Council Directive 96/61/EC[1];

(b) risks to and via the aquatic environment of discharges of the substance from a point source governed by the requirement for prior regulation referred to in Article 11 (3) and legislation adopted under Article 16 of Directive 2000/60/EC of the European Parliament and of the Council[2];

(c) risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC[3], Council Directive 93/42/EEC[4] or Directive 98/79/EC of the European Parliament and of the Council[5].

1 OJ L 257, 10.10.1996, p. 26.
2 OJ L 327, 22.12.2000, p. 1.
3 OJ L 189, 20.7.1990, p. 17.
4 OJ L 169, 12.7.1993, p. 1.
5 OJ L 331, 7.12.1998, p. 1.

Justification

Linked to Amendment 48.

Amendment 53
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 57, paragraph 6

6. Authorisations ***may*** be subject to conditions, including review periods and/or monitoring. Authorisations granted in accordance with paragraph 3 shall ***normally*** be subject to a time-limit.	6. Authorisations ***shall*** be subject to conditions, including review periods and/or monitoring. Authorisations granted in accordance with paragraph 3 shall be subject to a time-limit.

Justification

Self-explanatory.

Amendment 54
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 57, paragraph 7

7.The authorisation shall specify:	7.The authorisation shall specify:
(a) the person(s) to whom the authorisation is granted;	(a) the person(s) to whom the authorisation is granted;
(b) the identity of the substance(s);	(b) the identity of the substance(s);
(c) the use(s) for which the authorisation is granted;	(c) the use(s) for which the authorisation is granted;
(d) ***any*** conditions under which the authorisation is granted;	(d) ***the*** conditions under which the authorisation is granted;
(e) ***any*** review period;	(e) ***the*** review period;
(f) ***any*** monitoring arrangement.	(f) ***the*** monitoring arrangement.

Justification

Self-explanatory.

Amendment 55
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 58, paragraph 1

1. Authorisations ***granted in accordance with Article 57(3) which are subject to a time-limit*** shall be regarded as valid until the Commission decides on a new application, provided that the holder of the authorisation submits a new application at least 18 months before the expiry of the time-limit. Rather than re-submitting all elements of the original application for the current authorisation, the applicant may submit only the number of the current authorisation, ***subject to the second, third and fourth subparagraphs***.	1. Authorisations shall be regarded as valid until the Commission decides on a new application, provided that the holder of the authorisation submits a new application at least 18 months before the expiry of the time-limit. Rather than re-submitting all elements of the original application for the current authorisation, the applicant may submit only***:***
	(a) the number of the current authorisation,
If he cannot demonstrate that the risk is adequately controlled, he shall submit an update of the socio-economic analysis, analysis of alternatives and substitution plan contained in the original application***.***	***(b)*** an update of the socio-economic analysis, analysis of alternatives and substitution plan contained in the original application***,***
If he can now demonstrate that the risk is adequately controlled, he shall submit an update of the chemical safety report.	***(c)*** an update of the chemical safety report.
If any other elements of the original application have changed, he shall also submit updates of these element(s).	If any other elements of the original application have changed, he shall also submit updates of these element(s).

Justification

Linked to Amendment 48.

Amendment 56
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 58, paragraph 2

2. Authorisations ***may*** be reviewed at any time if the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact.	2. Authorisations ***shall*** be reviewed at any time if the circumstances of the original authorisation have changed so as to affect the risk to human health or the environment, or the socio-economic impact.

Justification

Self-explanatory.

Amendment 57
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 58, paragraph 4

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

Justification

Self-explanatory.

Amendment 58
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 59, paragraphs 4 and 5

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

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

Justification

Self-explanatory.

Amendment 59
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
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 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)***, (da)*** and ***(db)***.

Justification

Linked to Amendment 58.

Amendment 60
TITLE VII - AUTHORISATION
Chapter 2 - The granting of authorisations
Article 61, paragraph 4

4. The draft opinions shall include the	4. The draft opinions shall include the

following elements:	following elements:
(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: ***a check on the*** assessment ***(carried out by the applicant for authorisation)*** of the risk to health and/or the environment arising from the use(s) of the substance as described in the application;
(b) Socio-economic Analysis Committee: an assessment of the socio-economic factors associated with the use(s) of the substance as described in the application, when an application is made in accordance with Article 59***(5)***.	(b) Socio-economic Analysis Committee: ***a check on the*** assessment ***(carried out by the applicant for authorisation)*** 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***(da) and (db)***.

Justification

Linked to Amendment 58. Makes it clear that industry has prime responsibility for risk assessment and the assessment of socio-economic factors.

Amendment 61
TITLE VII - AUTHORISATION
Chapter 3 - Authorisations in the supply chain
Article 62 a (new)

	Requirement to label articles containing dangerous substances
	Producers and importers of articles containing substances which meet the authorisation criteria must ensure that the labelling indicates the presence of those substances and that the authorisation number is stated.

Justification

Articles containing dangerous substances must be labelled.

Amendment 62
TITLE IX - AGENCY
Article 72

Article ***72***	Article ***72a***

Justification

In the interests of greater clarity it is considered preferable for the tasks of the Agency to be indicated first and only then the constituent bodies thereof. The text of Article 72 is therefore placed after Article 73.

Amendment 63
TITLE IX - AGENCY
Article 73, paragraph 2

2. ***The Secretariat shall undertake the following tasks***:	2. ***The Agency shall in particular, through its committees***:
(a) ***performing the tasks allotted to it under Title II; including facilitating the efficient registration of imported substances, in a way consistent with the Community's international trading obligations towards third countries***;	(a) ***develop criteria for prioritising substances for evaluation and compile a list of priority substances for evaluation, pursuant to Title VI***;
(b) ***performing the tasks allotted to it under Title III***;	(b) ***draw up opinions on applications for authorisation, pursuant to Title VII***;
(c) ***performing the tasks allotted to it under Title VI***;	(c) ***take part in the procedure for adopting restrictions in respect of certain dangerous substances and preparations by preparing dossiers and drawing up opinions, pursuant to Title VIII***;
(d) ***establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list, making the non-confidential information identified in Article 116(1) in the data base(s) publicly available over the Internet, and making other non-confidential information in the databases available on request***;	(d) ***draw up proposals with a view to harmonising classifications and labelling at Community level, pursuant to Title X***;
(e) ***making publicly available information as to which substances are being, and have been evaluated within 90 days of receipt of the information at the Agency, in accordance with Article 116(1)***;	(e) ***at the Commission's request, provide technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity-building activities on sound management of chemicals in***

	developing countries;
(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 report****s*** ***by industry and especially by Small and Medium sized Enterprises (SMEs)***;	(f) ***at the Commission's or the European Parliament's request, draw up an opinion on any other aspects concerning the safety of substances on their own, in preparations or in articles***;
(g) ***providing technical and scientific guidance on the operation of the present Regulation for Member State competent authorities and providing support to the competent authorities' help desks established under Title XII***;	(g) ***at the Commission's request, draw up opinions relating to the revision of the criteria laid down in Articles 5, 6, 15 and 16 concerning the selection of substances for registration purposes with a view to including, inter alia, data relating to exposure risks and scenarios.***
(h) preparing explanatory information on this Regulation for other stakeholders;	
(i) at the Commission's request, providing technical and scientific support for steps to improve co-operation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries.	

Justification

This clarifies the Agency's tasks and those of its bodies, and makes them more transparent. The order of the paragraphs is therefore reversed in order to reflect the relative importance of the tasks carried out by the Agency.

Amendment 64
TITLE IX - AGENCY
Article 73, paragraph 3

3. ***The Committees shall undertake the following***:	3. ***The Agency shall, in particular via the Substance Information Exchange Forum***:
(a) ***performing the tasks allotted to them under Title VI***;	(a) ***spread good practice and highlight problems at Community level***;
(b) ***performing the tasks allotted to them***	(b) ***propose, coordinate and evaluate harmonised enforcement projects and***

under Title VII;	***joint inspections***;
(c) ***performing the tasks allotted to them under Title VIII***;	(c) ***coordinate exchanges of inspectors***;
(d) ***performing the tasks allotted to them under Title X***;	(d) ***identify enforcement strategies and minimum enforcement criteria***;
(e) ***at the Commission's request, providing technical and scientific support for steps to improve co-operation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries***;	(e) ***develop working methods and tools of use to local inspectors***;
(f) ***at the Commission's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in preparations or articles.***	(f) ***develop an electronic information-exchange procedure;***
	(fa) liaise with industry and other stakeholders, including relevant international organisations as necessary;
	(fb) cooperate with the Commission and the Member States with a view to promoting voluntary agreements between industry and other interested parties.

Justification

This clarifies the Agency's tasks and those of its bodies, and makes them more transparent. The order of the paragraphs is therefore reversed in order to reflect the relative importance of the tasks carried out by the Agency.

Amendment 65
TITLE IX - AGENCY
Article 73, paragraph 4

4. ***The Forum shall undertake the following tasks***:	4. ***In addition, the Agency shall***:
(a) ***spreading good practice and highlighting problems at Community level***;	(a) ***perform the tasks allotted to it under Title II, including facilitating the efficient registration of imported substances, in a***

	way consistent with the Community's international trading obligations towards third countries;
(b) proposing, co-ordinating and evaluating harmonised enforcement projects and joint inspections;	(b) ***perform the tasks allotted to it as regards the sharing of data and preventing superfluous experiments from being carried out, pursuant to Title III***;
(c) co-ordinating exchange of inspectors;	(c) ***perform the tasks allotted to it as regards information in the supply chain, pursuant to Title VI***;
(d) identifying enforcement strategies, as well as minimum enforcement criteria;	(d) ***establish and maintain database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list, make the non-confidential information identified in Article 116(1) in the data base(s) publicly available over the Internet, and make other non-confidential information in the databases available on request***;
(e) ***developing working methods and tools of use to local inspectors***;	(e) ***make publicly available information as to which substances are being, and have been, evaluated within 90 days of receipt of the information at the Agency, in accordance with Article 116(1)***;
(f) ***developing an electronic information exchange procedure***;	(f) ***provide technical and scientific guidance and tools where appropriate for the operation of this Regulation, in particular in order to assist the development of chemical safety reports by industry and especially by Small and Medium-Sized Enterprises (SMEs)***;
(g) ***liaising with industry and other stakeholders, including relevant international organisations, as necessary.***	(g) ***provide technical and scientific guidance on the operation of the present Regulation for Member State competent authorities and providing support to the competent authorities' help desks established under Title XII;***
	(ga) prepare explanatory information on this Regulation for other stakeholders;
	(gb) at the Commission's request, provide technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third

countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity-building activities on sound management of chemicals in developing countries.

Justification

This clarifies the Agency's tasks and those of its bodies, and makes them more transparent. The order of the paragraphs is therefore reversed in order to reflect the relative importance of the tasks carried out by the Agency.

Amendment 66
TITLE IX - AGENCY
Article 74

Article ***74***	Article ***75a***

Justification

In the interests of greater clarity it would be better to state first of all the composition of, and the arrangements for appointing, the Management Board, and then to describe its tasks. The text of Article 74 is therefore placed after Article 75.

Amendment 67
TITLE IX - AGENCY
Article 75, paragraph 1

1. The Management Board shall be composed of ***six*** representatives from Member States nominated by the Council and ***six representatives nominated*** by the Commission, as well as ***three*** individuals from interested parties nominated by the Commission without voting rights.	1. The Management Board shall be composed of ***eleven*** representatives from Member States nominated by the Council ***in consultation with the European Parliament, on the basis of a list drawn up by the Commission which includes substantially more names than the number of members to be nominated,*** and ***of one representative*** nominated by the Commission, as well as ***four*** individuals from interested parties ***(industry and consumer, worker and environmental protection organisations)*** nominated by the Commission without voting rights. ***The list drawn up by the Commission, together with the relevant documentation, shall be forwarded to the European Parliament. As soon as possible and at the latest within three months of receiving such communication the European Parliament may submit its own opinion to the Council, which shall nominate the Management Board.*** ***The members of the Management Board shall be nominated in such a way as to ensure the highest levels of competence, a wide range of relevant specialist knowledge and (without prejudice to such characteristics) the broadest possible geographical distribution within the European Union.***

Justification

This restates Parliament's traditional view (whilst maintaining the total number of members constant) as regards the composition of, and the arrangements for appointing, the Management Board. The number of representatives from interested parties is increased from three to four in order to enable all the relevant sectors to be included.

Amendment 68
TITLE IX - AGENCY
Article 77, paragraph 1

1. The ***meetings of the*** Management Board shall ***be*** convened by ***its*** Chairman.	1. The Management Board shall ***meet when*** convened by ***the*** Chairman ***or at the request of at least one-third of its***

members.

Justification

Self-explanatory.

Amendment 69
TITLE IX - AGENCY
Article 78

The Management Board shall establish rules of procedure for voting, including the conditions for a member to vote on behalf of another member. The Management Board shall act by a ***two-thirds*** majority of ***all*** members with the right to vote.	The Management Board shall establish rules of procedure for voting, including the conditions for a member to vote on behalf of another member. ***Unless otherwise provided*** the Management Board shall act by a majority of ***its*** members with the right to vote.

Justification

Following the change to the composition of the Management Board, there is no longer any need for such a large majority.

Amendment 70
TITLE IX - AGENCY
Article 79, paragraph 1

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

Justification

All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article, in the interests of greater clarity (see Amendment 84).

Amendment 71
TITLE IX - AGENCY
Article 79, paragraph 2, letter j a (new)

	(ja) establishing and maintaining contact with the European Parliament and ensuring that a regular dialogue is held

	with that body's relevant committees.

Justification

Self-explanatory.

Amendment 72
TITLE IX - AGENCY
Article 79, paragraph 3 a (new)

	Once the general report and the programmes have been adopted by the Management Board, the Executive Director shall forward them to the European Parliament, the Council, the Commission and the Member States, and shall arrange for them to be published.

Justification

Self-explanatory.

Amendment 73
TITLE IX - AGENCY
Article 80, paragraph 1

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

Justification

Linked to amendment 74.

Amendment 74
TITLE IX - AGENCY
Article 80, paragraph 2

2. The Executive Director of the Agency shall be appointed by the Management Board on the grounds of merit and	2. The Executive Director of the Agency shall be appointed by the Management Board***, which shall select from a list of***

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

Justification

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

Amendment 75
TITLE IX - AGENCY
Article 81, paragraph 1

1. Each Member State may ***nominate*** candidates ***to membership*** of the Risk Assessment Committee. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the members of the Committee from this list, ***including at least one member from each Member State that has nominated candidates***. Members shall be appointed for their role and experience in the regulation of chemicals and/or for	1. Each Member State may ***propose up to three*** candidates ***for appointment as members*** of the Risk Assessment Committee. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the ***twenty*** members of the Committee from this list, ***ensuring that the widest possible geographical distribution is achieved***. Members shall be appointed for their role and experience in the regulation of

their technical and scientific expertise in reviewing risk assessments of substances.	chemicals and/or for their technical and scientific expertise in reviewing risk assessments of substances.

Justification

The Management Board must be able to exercise a certain amount of discretion in the selection of the members of the Risk-Assessment Committee and the Socio-Economic Analysis Committee. A ceiling must also be placed on the number of committee members, particularly in view of the fact that it will be possible for five additional members to be co-opted and for consultants to be engaged.

Amendment 76
TITLE IX - AGENCY
Article 81, paragraph 2

2. Each Member State may ***nominate*** candidates ***to membership*** of the Socio-economic Analysis Committee. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the members of the Committee from this list, ***including at least one member from each Member State that has nominated candidates***. Members shall be appointed for their role and experience in the regulation of chemicals and/or for their expertise in socio-economic analysis.	2. Each Member State may ***propose up to three*** candidates ***for appointment as members*** of the Socio-economic Analysis Committee. The Executive Director shall establish a list of the nominees, which shall be published on the Agency's website. The Management Board shall appoint the ***twenty*** members of the Committee from this list, ***ensuring that the widest possible geographical distribution is achieved***. Members shall be appointed for their role and experience in the regulation of chemicals and/or for their expertise in socio-economic analysis.

Justification

The Management Board must be able to exercise a certain amount of discretion in the selection of the members of the Risk-Assessment Committee and the Socio-Economic Analysis Committee. A ceiling must also be placed on the number of committee members, particularly in view of the fact that it will be possible for five additional members to be co-opted and for consultants to be engaged.

Amendment 77
TITLE IX - AGENCY
Article 81, paragraph 3

3. Each Member State shall appoint one member to the Member State Committee.	3. Each Member State shall appoint one member to the Member State Committee. ***The chairman of the Member State***

	Committee shall be an employee of the Agency, nominated by the Executive Director.

Justification

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

Amendment 78
TITLE IX - AGENCY
Article 81, paragraph 5

5. The members of each Committee ***appointed following nomination by a Member State*** shall ensure that there is appropriate co-ordination between the tasks of the Agency and the work of their Member State competent authority.	5. The members of each Committee shall ensure that there is appropriate co-ordination between the tasks of the Agency and the work of their Member State competent authority.

Justification

Self-explanatory.

Amendment 79
TITLE IX - AGENCY
Article 81, paragraph 7

7. The Member States shall refrain from giving the members of the Risk Assessment Committee or of the Socio-Economic Analysis Committee, or their scientific and technical advisers and experts, any instruction which is incompatible with the individual tasks of those persons or with the tasks, responsibilities and independence of the Agency.	***Deleted***

Justification

All the provisions relating to the independence of the component parts of the Agency's bodies are brought together in a single article, in the interests of greater clarity (see Amendment 84).

Amendment 80
TITLE IX - AGENCY

Article 81, paragraph 9, second subparagraph

These rules shall in particular lay down the procedures for appointing and replacing the Chairman, replacing members, the procedures for delegating certain tasks to working groups, the creation of working groups and the establishment of a procedure for the urgent adoption of opinions. ***In the case of the Member State Committee, the Chairman shall be an employee of the Agency.***	These rules shall in particular lay down the procedures for appointing and replacing the Chairman, replacing members, the procedures for delegating certain tasks to working groups, the creation of working groups and the establishment of a procedure for the urgent adoption of opinions.

Justification

Linked to amendment 77.

Amendment 81
TITLE IX - AGENCY
Article 82, paragraph 1, subparagraph 1 a (new)

	The members of the Forum may not belong to the Management Board.

Justification

Self-explanatory.

Amendment 82
TITLE IX - AGENCY
Article 82, paragraph 3

3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups. ***The Member States shall refrain from giving the Forum members, or their scientific and technical advisers and experts any instruction which is incompatible with the individual tasks of those persons or with the tasks and responsibilities of the Forum.***	3. The members of the Forum shall be supported by the scientific and technical resources available to the competent authorities of the Member States. Each Member State competent authority shall facilitate the activities of the Forum and its working groups.

Justification

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

Amendment 83
TITLE IX - AGENCY
Article 83, paragraph 1

1. Where, in accordance with Article 73, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XIV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. ***For each case, rapporteurs and co-rapporteurs shall undertake to act in the interests of the Community and shall make a declaration of commitment to fulfil their duties and a declaration of interests in writing.*** A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.	1. Where, in accordance with Article 73, a Committee is required to provide an opinion or consider whether a Member State dossier conforms with the requirements of Annex XIV, it shall appoint one of its members as a rapporteur. The Committee concerned may appoint a second member to act as co-rapporteur. A member of a Committee shall not be appointed rapporteur for a particular case if he indicates any interest that might be prejudicial to the independent consideration of that case. The Committee concerned may replace the rapporteur or co-rapporteur by another one of its members at any time, if, for example, they are unable to fulfil their duties within the prescribed time limits, or if a potentially prejudicial interest comes to light.

Justification

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

Amendment 84
TITLE IX - AGENCY
Article 84

Qualification and interests of members of committees and boards	***Independence***

1. The membership of the Committees and of the Forum shall be made public. ***Individual members may request that their names not be made public if they believe that such publication could place them at risk. The Executive Director shall decide whether to agree to such requests.*** When each appointment is published, the professional qualifications of each member shall be specified.	1. The membership of the Committees and of the Forum shall be made public. When each appointment is published, the professional qualifications of each member shall be specified.
2. Members of the Management Board, the Executive Director ***and*** members of the Committees ***and*** of the Forum shall make a declaration of ***commitment to fulfil their duties and a declaration of interests which could be considered to be prejudicial to their independence. These declarations shall be made annually in writing***.	2. Members of the Management Board, the Executive Director***,*** members of the Committees***, members*** of the Forum***, members of the Board of Appeal, experts and scientific and technical advisers shall not have economic or other interests in the chemical and related industries which may prejudice their impartiality. They shall endeavour to act independently and in the public interest and*** shall ***each year*** make a declaration of ***their financial interests. Any indirect interests relating to the chemical industry shall be declared in a register held by the Agency and accessible to the public on request at the Agency's offices***. ***The Agency's code of practice shall specify measures relating to the application of this article, with particular reference to the acceptance of gifts.***
3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees ***and*** of the Forum and any experts participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall neither participate in the discussion of the relevant agenda points nor in any voting thereupon.	3. At each of their meetings, members of the Management Board, the Executive Director, members of the Committees***, the members*** of the Forum***,*** and any experts ***and scientific and technical advisers*** participating in the meeting shall declare any interests which could be considered to be prejudicial to their independence with respect to any points on the agenda. Anyone declaring such interests shall neither participate in the discussion of the relevant agenda points nor in any voting thereupon. ***Such declarations shall be made publicly accessible.***

Justification

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

Amendment 85
TITLE IX - AGENCY
Article 85, paragraph 3

3. The Chairman, the other members and the alternates shall be appointed by the Management Board on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures from a list of qualified candidates ***adopted*** by the Commission.	3. The Chairman, the other members and the alternates shall be appointed by the Management Board***, which shall select*** from a list of qualified candidates ***proposed*** by the Commission ***following a public-selection procedure advertised by means of a call for expressions of interest published in the Official Journal of the European Union and in other periodicals or on Internet sites. The members of the Board of Appeal shall be selected*** on the basis of their relevant experience and expertise in the field of chemical safety, natural sciences or regulatory and judicial procedures.

Justification

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

Amendment 86
TITLE IX - AGENCY
Article 86, paragraphs 2 and 3

2. The Members of the Board of Appeal shall be independent. In making their decisions they shall not be bound by any instructions.	***Deleted***
3. The members of the Board of Appeal may not perform any other duties in the Agency. ***The function of the Members may be a part-time function.***	3. The members of the Board of Appeal may not perform any other duties in the Agency.

Justification

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

Amendment 87
TITLE IX - AGENCY
Article 105

The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of industry, consumer protection***, worker protection and*** environmental protection organisations. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.	The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of industry ***and workers and of*** consumer protection, environmental protection ***and animal protection*** organisations. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission.

Justification

Like other organisations, organisations for the protection of animals are deemed to be interested parties and they are therefore represented for the purposes of this article.

Amendment 88
TITLE IX - AGENCY
Article 106

To ensure transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of chemicals ***which is not of a confidential nature.***	To ensure ***maximum*** transparency, the Management Board shall, on the basis of a proposal by the Executive Director and in agreement with the Commission, adopt rules ***and set up a registry*** to ensure the availability to the public of regulatory, scientific or technical information concerning the safety of chemicals***, pursuant to Regulation (EC) No 1049/2001.*** ***The internal rules of procedure of the Agency and of the committees and working parties thereof shall be made***

	available to the public via the Agency and on the Internet.
	A copy of all scientific information (except for confidential information of a commercial nature) shall be made available to interested parties upon written request. The applications for authorisation submitted, the stage reached in the procedure, interim decisions, authorisations and any other condition or restriction imposed shall be published on the Internet in a comprehensible form.

Justification

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

Amendment 89
TITLE X - CLASSIFICATION AND LABELLING INVENTORY
Article 110, paragraph 3

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.	3. Where the obligation under paragraph 1 results in different entries on the inventory for the same substance, ***the Agency shall establish the*** entry to be included in the inventory.

Justification

Self-explanatory.

Amendment 90
TITLE XI - INFORMATION
Article 114, paragraph 1, first subparagraph

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 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. ***The report shall record the experience acquired (including***

	through the implementation of voluntary agreements between industry and other interested parties) as regards application of the Regulation.

Justification

In addition to what is provided for in the legislation, the parties affected by the Regulation may conclude voluntary agreements.

Amendment 91
TITLE XI - INFORMATION
Article 114, paragraph 2, second subparagraph

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 five years after the date ***upon which this Regulation comes into force.***

Justification

Linked to the amendment to Article 133.

Amendment 92
TITLE XI - INFORMATION
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 ten years, the Commission shall publish ***(and shall forward to the European Parliament and to the Council)*** a general report on the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1 and 2.
However, the first report shall be published six years after the date ***of the notification required under Article 131(2)***.	However, the first report shall be published six years after the date ***upon which this Regulation comes into force***.

Justification

Linked to the amendment to Article 133.

Amendment 93
TITLE XIII - ENFORCEMENT
Article 122

Member States shall maintain a system of official controls and other activities as appropriate to the circumstances.	Member States shall maintain a system of official controls and other activities as appropriate to the circumstances. ***The Commission shall lay down guidelines for the implementation of this article.***

Justification

Self-explanatory.

Amendment 94
TITLE XIV - TRANSITIONAL AND FINAL PROVISIONS
Article 133, paragraph 1

1. ***Twelve*** years after entry into force of this Regulation, the Commission shall carry out a review with a view to the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. On the basis of this review, the Commission may, in accordance with the procedure referred to in Article 130(3), extend this obligation.	1. ***Six*** years after entry into force of this Regulation, the Commission shall carry out a review with a view to the application of the obligation to perform a chemical safety assessment and to document it in a chemical safety report to substances not covered by this obligation because they are not subject to registration or subject to registration but manufactured or imported in quantities of less than 10 tonnes per year. On the basis of this review, the Commission may, in accordance with the procedure referred to in Article 130(3), extend this obligation.

Justification

The Regulation should be reviewed at the same time as the first Commission report on the functioning thereof is submitted.

Amendment 95
TITLE XIV - TRANSITIONAL AND FINAL PROVISIONS
Article 133, paragraph 3 a (new)

	3a. The report referred to in the second subparagraph of Article 144(3) shall be accompanied, where justified, by a legislative proposal drawn up for the purpose of reviewing the criteria laid down in Articles 5, 6, 15 and 16 relating to the selection of substances for registration purposes with a view to

including, inter alia, data relating to exposure risks and scenarios.

Justification

Self-explanatory.

Amendment 96
Annex I, paragraph 0.6

0.6. The main element of the exposure part of the chemical safety report is the description of the manufacturer's or importer's exposure scenario(s) and the exposure scenario(s) recommended by the manufacturer or importer to be implemented ***for the identified use(s)***. The exposure scenarios contain a description of the risk management measures which the manufacturer or importer has implemented and recommends to be implemented by downstream users. If the substance is placed on the market, these exposure scenarios including the risk management measures shall be summarised in an annex to the safety data sheet in accordance with Annex IA.	0.6. The main element of the exposure part of the chemical safety report is the description of the manufacturer's or importer's exposure scenario(s) and the exposure scenario(s) recommended by the manufacturer or importer to be implemented ***by the downstream users, so that use can be made without risk to human health and to the environment***. The exposure scenarios contain a description of the risk management measures which the manufacturer or importer has implemented and recommends to be implemented by downstream users. If the substance is placed on the market, these exposure scenarios including the risk management measures shall be summarised in an annex to the safety data sheet in accordance with Annex IA.

Justification

The burden of obligations on downstream users should be lightened by requiring suppliers to incorporate a range of intended uses into their safety report.

Amendment 97
Annex I, paragraph 0.7

0.7. The level of detail required in describing an exposure scenario will vary substantially from case to case, depending on the use of a substance, its hazardous properties and the amount of information available to the manufacturer or importer. Exposure scenarios can describe the	0.7. The level of detail required in describing an exposure scenario will vary substantially from case to case, depending on the ***professional or industrial*** use of a substance, its hazardous properties and the amount of information available to the manufacturer or importer. Exposure

appropriate risk management measures for ***several individual uses of a*** substance. ***Single exposure scenarios may thereby cover*** large ranges of uses.	scenarios can describe the appropriate risk management measures for ***the*** substance, ***covering*** large ranges of uses.

Justification

The burden of obligations on downstream users should be lightened by requiring suppliers to incorporate a range of intended uses into their safety report.

Amendment 98
Annex I, paragraph 5.1.1

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:	5.1.1. Exposure scenarios shall be developed for manufacture in the Community, manufacturer's and importer's own use, and ***for the*** 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. 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:
- the processes involved in the production by the manufacturer and, if relevant, the further processing and use by the manufacturer or importer, including the physical form in which the substance is manufactured, processed and/or used;	- the processes involved in the production by the manufacturer and, if relevant, the further processing and use by the manufacturer or importer, including the physical form in which the substance is manufactured, processed and/or used;
- the processes involved in the ***identified*** use of the substance ***foreseen by the manufacturer or importer***, including the physical form in which ***the substance*** is processed and/or used;	- the processes involved in the use of the substance, including the physical form in which ***it*** is processed and/or used;

Justification

The burden of obligations on downstream users should be lightened by requiring suppliers to incorporate a range of intended uses into their safety report.

EXPLANATORY STATEMENT

BACKGROUND

The process of drawing up this Regulation is known to have been a lengthy, complex and controversial one; two years elapsed between the adoption of Parliament's opinion on the White Paper (November 2001) and the adoption of the proposal by the Commission. The process was a tortuous one in which stakeholders were extensively involved: over 6000 opinions were expressed by means of the on-line consultation launched in May 2003 in respect of the initial draft. This constituted a rich harvest of critical assessments and counter-proposals which prompted the Commission to amend the original text significantly. The principles and the objectives of this thorough reform of EU chemicals law - i.e. the protection of human health and of the environment - have been left untouched, but greater attention has been paid to the aspects relating to the competitiveness of EU industry as a whole and not just of the chemicals sector, since the Regulation also involves (by means of certain obligations) 'downstream users' who are affected by the 'upstream' effect created by the substitution of certain substances which will in all likelihood occur when the new rules are implemented. The result is a final text which - as the appended socio-economic impact assessment demonstrates - will significantly reduce costs.

OVERVIEW

The rapporteur considers that a satisfactory balance has been achieved between, on the one hand, competitiveness and innovation and, on the other, the protection of human health and of the environment. Such a balance essentially reflects Parliament's position regarding the White Paper, which the rapporteur has taken as a starting point and which gave the green light to the adoption of the new REACH system: Registration, Evaluation, Authorisation and Restriction of Chemicals. The balance must not be upset but, at the same time, it may also be significantly consolidated and improved, particularly with a view to increasing the system's effectiveness and its degree of certainty.

From this very general view the rapporteur draws a highly specific political conclusion: that he should submit a draft report which is firmly focused on certain priorities relating specifically to the functioning and functionality of REACH and which deals with other detailed aspects (for example, those contained in the Annexes) only as a secondary consideration and in the light of the debate on the draft report which will take place within the Environment Committee and the other Parliament committees which have been asked for their opinion on the proposal for a regulation.

PRIORITIES

1. Registration
2. Evaluation
3. Authorisation and Substitution
4. Agency

REGISTRATION

The Commission proposal lays down a requirement for registration in respect of all substances produced or imported in quantities of one tonne or more per year (on-site isolated intermediates or transported isolated intermediates). On the other hand, registration is not required in the case of substances produced or imported in quantities of less than one tonne per year, substances intended for use in research activities (five years and possibly a further five years up to a maximum of 15 years for pharmaceutical products) and polymers. It should be pointed out that for amounts under 10 tonnes per year the tests are simplified; the information required is directly proportionate to the volumes produced and to the risk; in particular, in the case of existing substances (which account for most of those to be incorporated into the system) the procedure is to be staggered whereby the final stage (covering substances in quantities of one tonne or more per year and substances in manufactured articles) will take place 11 years after the Regulation comes into force.

It is quite clear that this is the crucial (and, in certain respects, the most delicate) stage of the scheme, since it is designed to create (within the European Chemicals Agency) the general knowledge base which will be used at subsequent stages, in particular the evaluation and possible restriction of substances in their various uses and grades of exposure. It is entirely natural, therefore, that a public debate on the suitability of the criteria adopted by the Commission for the purpose of prioritising the incorporation of substances into the system should have arisen and still be open. In particular, the question has been asked as to whether a purely quantitative criterion (annual tonnage) is misleading and ultimately likely to generate excessive and expensive documentation of questionable value. From various quarters came the suggestion that such a criterion could be replaced by (or incorporated into) other, qualitative, criteria such as inherent hazardousness, use and exposure. The rapporteur considers such criticisms to be not without foundation and he is therefore willing to evaluate (and possibly adopt) any proposal which is capable of improving the Commission draft along such lines. At the current stage, however, he considers that the proposed model should be kept unchanged, especially in view of the fact that it appears to be the only one capable of providing all the parties involved in the system with an adequate degree of legal certainty.

The rapporteur therefore intends to restrict himself for the time being to two types of amendment:

1. establishment of a single registration system for substances contained in articles, on the one hand by abolishing the virtually universal procedure of notifying the Agency and, on the other, by tightening up the requirement to register potentially more harmful substances which are highly likely to be released under conditions of normal use;

2. further relaxing of the obligations to be imposed on downstream users as regards the provision of indications to suppliers of chemical substances or preparations - for example, by requiring such suppliers to include a range of intended uses in their Chemical Safety Report (CSR).

EVALUATION

The proposal for a Regulation provides for two types of evaluation: of dossiers and of

substances. The most problematic elements relate to the second type, with particular regard to the relationship between the European Agency and the Member States' competent authorities. There have been many complaints about the excessive complexity of the procedures laid down and, in particular, there are fears that excessive decentralisation of decision-making may lead to differences in behaviour between countries, thereby distorting the internal market.

The rapporteur considers that, in order to remedy these obvious disadvantages, action should be taken essentially in two areas:

1. The arrangements for devising national substance-evaluation rolling programmes. It is considered preferable for the Agency (and not the Member States' competent authorities) to be given the job of drawing up the list of priority substances for evaluation and not just (as provided for in the Commission proposal) the criteria for determining the order of priority. It should be pointed out that this change will enable the quality of the system to be improved, since it is at this stage (and not at the registration stage) that a combination of criteria which involve more than just the tonnage bands and include risks and exposure should be brought into play.

2. Simplification of the procedure, to be achieved by strengthening the role of the Agency, which will adopt a draft decision relating to a given substance without further involving the Member States' competent authorities which initially examined the draft. Such a step is possible on account of the fact that the dossier must be closely examined by the Member State Committee, without whose unanimous agreement the final decision passes to the Commission.

AUTHORISATION AND SUBSTITUTION

Authorisation will be required for certain categories of highly problematic substances: c/m/r categories 1 and 2, PBT, vPvB, substances which have equivalent effects on people and on the environment, and POPs which are subject to authorisation in view of the restrictions which are already provided for in the Stockholm Convention. Authorisation is granted when it can be demonstrated that the risks stemming from the use of such a substance can be adequately controlled. If this is not the case, authorisation may be granted on valid socio-economic grounds and in the absence of available technological alternatives. In such a case a substitution forecast must be submitted and a time-limit may be established. The Agency will have a period of ten months within which to draw up its opinion and non-confidential information will be published on the Agency's website , whilst the final decision will lie with the Commission.

This is a highly delicate issue from both the health and environment point of view and from the point of view of boosting innovation and promoting, in the medium and long term, substances and technologies which are more environmentally compatible.

The rapporteur's view is that the proposed sequence should be reversed, with the importance of the (conceptually and legally rather problematic) 'adequate control' clause as an initial criterion for the granting of authorisation being reduced and the link between authorisation (and the renewal or review thereof) and the substitution principle being made clearer and more forceful.

This could mean that:

- authorisation is granted if the socio-economic advantages outweigh the risks to human health and the environment, if it can be demonstrated that adequate alternative substances and technologies do not exist and if the substance is adequately controlled;

- the relevant applications must be supported by documentation including a valid socio-economic analysis and an analysis of the alternatives;

- the authorisation must indicate in a clear, binding fashion the terms and conditions to which it is subject, its period of validity and date of subsequent review, and the monitoring measures;

AGENCY

One of the most important decisions proposed in the Regulation is the establishment of a European Chemicals Agency. In order to be able to perform its tasks the Agency comprises various bodies: a Management Board, an Executive Director, a Committee for Risk Assessment, a Committee for Socio-Economic Analysis, a Member State Committee, a Forum for Exchange of Information on Enforcement, a Board of Appeal and a Secretariat.

This is obviously the structure which supports the entire system, the functioning of which depends crucially upon the way in which the Agency takes part (with a guiding role) in the restriction, evaluation and authorisation stage.

For this reason the rapporteur - in the preceding chapters and in particular in the one concerned with evaluation - has already indicated ways in which the Agency's central role could be strengthened. Those ways should be reflected in a specific article of the Regulation which stipulates the Agency's mission and tasks. In the Commission proposal, these seem to be indicated in a rather confused and disorganised fashion.

The text should therefore be extensively rewritten as regards all the aspects relating to the institutional model proposed: composition of the various bodies; arrangements for forming the component parts of those bodies and for selecting candidates; a clearer statement of the principles of transparency and independence; relations with the Community institutions. Since these are highly delicate issues which are frequently the subject of tedious institutional disputes, the rapporteur believes that what was agreed in respect of other comparable agencies (in particular the European Agency for the Evaluation of Medicinal Products) may usefully be taken as a basis. Such agencies are comparable from the point of view of the purpose they serve (i.e. safeguarding the general public) and also from the no-less important point of view of providing the highest levels of scientific quality and independence, transparency and public information.

The rapporteur points out that, at the 12 December 2003 Brussels European Council, a political agreement was reached on the location of a variety of European agencies. Pursuant to that agreement the European Chemicals Agency will have its seat in Finland.

This decision runs counter to the proposal put forward by the Commission in its Regulation: namely, that the agency could have its seat at the Joint Research Centre in Ispra, where the

European Chemicals Bureau already operates and where other, related tasks are performed.

On this topic the rapporteur merely comments that the Commission's proposed seat would be more appropriate for obvious reasons relating to the rational use of resources.

Clearly, the European Council's decision opens up a sensitive institutional issue, since Parliament has been deprived (after having specifically had it for the first time) of its power of codecision regarding the Agency's seat. It has been presented with a *fait accompli* which calls into question complex balances and national interests.

Consequently, the rapporteur feels he should express a view on the issue only after hearing the opinion of the relevant committee and following the initial parliamentary debate.

REPORT AND REVISION

For the reasons already put forward in the other sections of this document (particularly in the section relating to registration), the rapporteur considers lastly that he should intervene in respect of the provisions laid down on the subject of monitoring and possible revision of the Regulation.

His proposal is to bring forward and to align the two deadlines set for the first report on the functioning of REACH and for the possible revision thereof, with particular reference to the criteria for selecting the substances subject to registration.