NGOs' five key demands to improve REACH

1. **An authorisation for the use of 'chemicals of very high concern' should only be granted if no safer alternatives are available and the use is essential to society. We believe the substitution principle must be mandatory in this process.**

Only when the loophole of 'adequate control' has been deleted will REACH give a clear signal on which chemicals need to be used less or removed from use. Otherwise, perfectly acceptable, safer alternatives will be sidelined and withheld from chemical users, and consumers will continue to be exposed to unacceptable risks.

2. **Registration procedures must close the existing gap in safety information.**

In the proposed new regulation, 20,000 chemicals have been excluded from a proper safety assessment. The three (non-animal) tests plus the Chemical Safety Report removed from the registration requirements for 1-10 tonne per annum chemicals must be reinstated in order to provide sufficient information to evaluate the hazards, exposures and safe uses of chemicals. Without sufficient information, including biodegradability tests and exposure information, chemicals cannot be classified according to their danger or prioritised for further action.

3. **Industry information needs independent quality control.**

REACH provides industry with a unique opportunity to take responsibility for chemicals safety. This will only work if sufficient quality auditing and regulatory quality control is supplied to guarantee the reliability of the information provided. All registration dossiers should be quality audited by an independent third or certified party, without a conflict of interest, and at least 5% of all registration dossiers must be evaluated by the national authorities.

4. **Chemicals used in imported articles must have the same information requirements as those in EU-made articles.**

The current proposal's weak requirements on substances in articles could allow EU companies to import articles from outside the EU containing chemicals not registered and/or maybe even banned or restricted under REACH. This loophole will not properly protect consumers from unsafe chemicals in imported products. It may also create a competitive disadvantage on certain sectors of EU manufacturing industry. Europe is the world's biggest market for consumer goods so it should provide leadership in setting new global safety standards.

5. **There must be a public right to know and improved procedures on access to information throughout the supply chain.**

Consumers and retailers should be able to find out about chemicals in the products they are paying for, particularly potentially harmful ones. Currently, the information flow stops once a chemical enters an article, denying users and consumers downstream the chance to choose between alternatives. Information should be handed down the entire manufacturing chain to enable retailers and consumers to know if chemicals of very high concern are present in finished articles. Articles should be labelled if authorised chemicals are present. The procedure for obtaining information from the chemical Agency is currently time-consuming and inefficient and

we believe it is not compliant with the Aarhus Convention. Therefore, it needs to be streamlined and improved. The list of non-confidential information in REACH needs to be extended to include the names of registrants, volume categories and exposure information.

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CONTENT

I. DUTY OF CARE AND SCOPE

The registration requirements of REACH do not apply to a considerable number of chemicals and uses, for example those 70,000 chemicals used at less than 1 tonne per annum. Moreover, due to phase-in deadlines, it will be many years before all the existing chemicals have to be registered.

- **A legally-binding duty of care for all chemical manufacturers and users, making them responsible for the safety of their products is needed to fill this gap**. REACH is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market, import or use substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle. This includes the duty to characterise, document and communicate in a transparent and appropriate manner the risks arising from the manufacture, use and disposal of such substances. When selecting substances for production and use, manufacturers and downstream users shall select the safest available substance.

The scope of REACH should not be further limited. The industry proposal to base REACH on marketed volume, instead of the volume produced, would not only reduce the scope of REACH, but it would also allow continued export of non-registered and potentially risky chemicals. These chemicals could threaten people's health outside the EU and/or come back to Europe via products and transboundary pollution. Furthermore, this limitation of the scope would be contradictory to Europe's international commitment to ensure a sound management of chemicals by 2020 (WSSD) and to the OSPAR Convention in which the objective *"of cessation of discharges, emissions and losses of hazardous substances by the year 2020"* has been fixed.

Amendment 1
Article 1, paragraph 3

This Regulation is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle.	This Regulation is based on the principle that it is up to manufacturers, importers and downstream users to ensure that they manufacture, place on the market, import or use such substances that do not adversely affect human health or the environment. Its provisions are underpinned by the precautionary principle. ***This includes the duty to characterise, document and communicate in a transparent and appropriate manner the risks arising from the manufacture, use and disposal of such substances. When selecting substances for production and use, manufacturers and downstream users shall select the safest available substance.***

Justification

The duty of care has been completely deleted from the Commission's proposal. But REACH does not deal with all chemicals for all uses (e.g. 70,000 chemicals below 1 tpa). Therefore it is considered important for human and environmental protection to place a general duty of care on all chemical manufacturers and users. This would do nothing more than codify the voluntary commitments of the chemicals industry (e.g. responsible care programme).

A duty of care will guarantee that industry has to produce and make available basic safety information for all chemicals in use, regardless of whether they are registered or not.

II. REGISTRATION

Registration is a key foundation of REACH. It is essential to ensure that decisions on the regulation and use of chemicals are based on knowledge about each substance, not ignorance. It is not possible to prioritise or make decisions on chemicals without such information. REACH finally provides the opportunity to oblige the chemical industry to provide safety information on the products it has been selling since before 1981.

Industry has the responsibility for providing sufficient toxicity data on all their chemicals in order to enable high-quality risk management decisions to be taken for the protection of the environment and human health. In particular, it is crucial that enough information is provided to identify those chemicals of very high concern.

The Commission has provided a number of mechanisms to encourage, and in the case of vertebrate data, force data sharing within the registration procedure. However, we consider that there is merit in examining whether it would be possible to ask for one registration per substance (OSOR), as is being suggested by the UK and Hungary. The advantages of a one registration per substance approach include: a reduction in the administrative burden by reducing the number of individual registrations; more accurate information in the market as the dossier will need to be agreed by all manufacturers and importers; quicker processing of registration packages; and easier access to the information on any one substance by downstream users and other interested parties.

However, it is very important that any change in the REACH proposal of this nature does not dilute the **individual responsibility of producers and importers for the chemicals they are producing or importing**. For example, the REACH text ensures that a manufacturer of a chemical must accept responsibility for producing exposure scenarios for downstream users in their supply chain. This responsibility needs to be retained as it is a crucial mechanism within REACH to create individual responsibility for producers and to provide increased security for downstream users of chemicals. Provided these responsibilities are clearly retained, we support the concept of one registration per chemical.

2.1. General registration requirements

Registration is a crucial mechanism within REACH to create individual responsibility for manufacturers and importers of chemicals, and to provide increased security for downstream users of chemicals. However, this opportunity for industry to take responsibility for chemicals safety will only work if sufficient quality auditing is provided to guarantee the reliability of the information submitted.

The key improvements we propose are as follows:

- **All registration dossiers should be audited for their quality by an independent third or certified party, without a conflict of interest (new Article 5 (4a));**
- **Chemical manufacturers shall clearly indicate to downstream users if there are uses they advise against in the Chemical Safety Report (Article 9 (a) (v));**
- **All substances of very high concern (and not only CMRs as in the Commission proposal) should be prioritised for registration (Article 21 (1) (a)).**

Some industry proposals argue that the current Commission's proposal for prioritisation should be replaced by a 'risk-based' one based on Safety Data Sheets, although these are known to be generally poor quality as indicated in a recent survey by Member State authorities finding that only 31% were fully correct.

In addition, there are two major arguments against such a prioritisation:

- **It is impossible to prioritise without sufficient safety information** and it is the registration procedure that brings in the safety information which allows for a prioritisation in the following stages (evaluation, authorisation, and restrictions);
- **Tonnage produced is an enforceable and legally certain measure.**

Therefore we consider that the Commission's proposal for prioritising chemicals is the most reliable and legally predictable way to proceed with registration. Tonnage bands are the best way to bring chemicals into the registration system, combined with prioritisation of particular hazardous properties (CMR, PBT, vPvB).

Amendment 1
Article 5, paragraph 4a (new)

All submissions for registration should be independently audited prior to their submission to the Agency, and the audit report should be submitted to the Agency with the submission for registration. This audit should ensure that the registration is complete and reasonable. The audit should be carried out by an organisation independent of the registrant, though the cost should be met by the registrant. The Agency will formulate guidance on such quality audits.

Justification

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

Amendment 2
Article 9, point (a), indent (v)

(v) guidance on safe use of the substance as specified in Section 5 of Annex IV;	(v) guidance on safe use of the substance as specified in Section 5 of Annex IV**, *including guidance on uses that the registrant advises against*;**

Justification

This ensures that producers clearly indicate to downstream users if there are uses they advise against. It could be argued that if a use is omitted from an exposure scenario then a downstream user should treat this as a use that is advised against. However, this is clearly not always going to be the case, and is not a clear way of indicating problems to downstream users. We therefore suggest that provision be made to encourage the registrant to list specific uses and exposure scenarios that they advise against.

Amendment 3
Article 21, paragraph 1, point (a)

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

into force of this Regulation;	more per year per manufacturer or per importer, at least once following the entry into force of this Regulation;

Justification

The first deadline for registration of phase-in substances (3 years) covers only CMR-substances in Category 1 and 2. This first registration stage should also cover known PBTs, vPvBs and other substances of very high concern as an improvement of the prioritisation system to cover very high concern chemicals first. These substances can then be channelled into the authorisation scheme as soon as possible.

2.2. Information on low-volume chemicals

The key step that determines the scope of REACH is the registration procedure. The registration requirements vary by tonnage produced or imported per manufacturer/importer, and they are prioritised so that higher volume chemicals (a recognised proxy for exposure) require more safety information.

We are very concerned that chemicals produced in low volumes will not be sufficiently addressed under REACH. For many 1-10 tpa chemicals there will be no obligation to produce a safety data sheet due to lack of proper classification.

Indeed, the information required for the chemicals produced at 1-10 tpa will make it difficult to identify which chemicals would meet the criteria of very high concern or those which might pose a risk to human health.

Therefore, several improvements of the Commission's proposal are needed to ensure that information requirements on low volume chemicals enable proper risk management and contribute to a high level of protection of human health and the environment.

The key improvements we propose are as follows:

- **Chemical Safety Report for low volume chemicals should be required** to ensure that suppliers examine hazards and exposures and communicate safe uses to downstream users, so that appropriate risk management measures are set up to protect workers or consumers who are in direct contact with these chemicals, e.g. additives in cloth dyes or cosmetics (Article 13(1));
- **Three non-animal safety tests should be re-introduced in Annex V** as standard information requirements for substances manufactured or imported in quantities of 1 tonne or more. This will ensure the identification of substances of very high concern for low volume chemicals, which is the prerequisite for a proper risk management within REACH. These three additional tests include the *in vitro* cytogenicity study in mammalian cells (a non-animal test that helps to verify carcinogenic/mutagenic properties), the growth inhibition study on algae which will provide an initial indication of chronic toxicity in aquatic environment; and finally degradation tests which investigates whether the chemical breaks down in the environment. The reintroduction of these three tests will make certain that all relevant existing data is brought forward on all REACH chemicals, which would include all toxicity data beyond those end-points that must be covered by the registration requirements.

Amendment 1
Article 13, paragraph 1

Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter if the registrant manufactures or imports such a substance in quantities of ***10*** tonnes or more per year.	Without prejudice to Article 4 of Directive 98/24/EC, a chemical safety assessment shall be performed and a chemical safety report completed for all substances subject to registration in accordance with this Chapter if the registrant manufactures or imports such a substance in quantities of ***1 tonne*** or more per year.
The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and Annex I for either each substance on its own or in a preparation or a group of substances.	The chemical safety report shall document the chemical safety assessment which shall be conducted in accordance with paragraphs 2 to 7 and Annex I for either each substance on its own or in a preparation or a group of substances.

Justification

The information required for the chemicals produced at 1-10 tpa is inadequate, and will be insufficient to identify which would meet the criteria of very high concern or those which might pose a risk to human health. Unfortunately, the REACH text has been significantly weakened as compared to the internet text, with 3 tests removed, and the obligation to produce a Chemical Safety Report deleted for these chemicals. This lack of classification information could lead to REACH not requiring many of the 1-10 tonne substances to have safety data sheet. Without such basic information, it will be difficult to for downstream users to implement appropriate risk management measures to protect workers or consumers.

Amendment 2
Annex V

Re-introduction of 3 tests:

In vitro cytogenicity study in mammalian cells (non-animal test that helps to verify carcinogenic/mutagenic properties); growth inhibition study on algae (initial indication of chronic toxicity in aquatic environment); degradation tests (information on whether the chemicals breaks down in the environment) to ensure that all relevant existing data is brought forward on all REACH chemicals, which would include all toxicity data beyond those end-points that must be covered by the registration requirements.

Justification

The re-introduction of these 3 safety tests in Annex V (Standard information requirements for substances manufactured or imported in quantities of 1 tonne or more) will ensure the identification of substances of very high concern for low volumes chemicals, which is the prerequisite for a proper risk management within REACH.

2.3. Substances in articles

The current REACH proposal for dealing with registration of substances in articles (Article 6) is not robust enough to ensure a high level of protection of public health and the environment. We consider that the weakest component is the tonnage limit of 1 tonne chemical **per article type**. This will create a legal nightmare with regard to enforcement of the legislation, as importers will be able to divide their imports into numerous article types (red chairs, blue chairs, chairs with arms etc all separately), and argue that the 1 tonne threshold is not being breached by any individual article type.

We consider that public health and the environment would be better protected if:

- **The registration threshold for chemicals in imported articles were calculated per importer rather than per article type** as occurs with substances and preparations**.** For substances and preparation, an importer of preparations must register an import of 1 tonne or more per annum of substance, regardless of how many containers they use to bring it in, or the shape of these containers.

- **Our solution will also remove the obligation for importers to assess the likelihood of release and the likely toxicity of the chemical concerned,** both of which would be very difficult requirements for an importer.

Such a provision would effectively oblige the importer to inform their suppliers that they should only use chemicals registered under REACH or, in exceptional circumstances, that they must register a chemical. Given that the substances in articles procedures will only come into force once phase-in registrations are completed for all substances, i.e. around 2018, industry will have plenty of time to adapt to this situation until then. It is clear that the EU registration database, globally available on the internet will then contain the vast majority of chemicals needed, as any producer manufacturing articles in Europe will be using registered chemicals.

Amendment 1
Article 6, paragraph 1

Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles**,** if all the following conditions are met:	Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles**,** if all the following conditions are met:
(a) the substance is present in those articles ***in quantities totalling*** over 1 tonne per producer or importer per year, ***each article type being considered separately;***	(a) the substance is present in those articles ***in a cumulative quantity of*** 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 substance is intended to be released under normal and reasonably foreseeable conditions of use.***	

Justification

The weakest component is the tonnage limit of 1 tonne chemical per article type. This will create a legal nightmare in any attempt at enforcement, as importers will be able to divide their imports into numerous article types (red chairs, blue chairs), and argue that the 1 tonne threshold is not being breached by any individual article type. We consider that public health and the environment would be better protected if the registration threshold for chemicals in imported articles were calculated per importer rather than per article type, as occurs with substances and preparations.

Amendment 2
Article 6, paragraph 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 is made known, that the substance is likely	

to be released under normal and reasonably foreseeable conditions of use, even though this release is not an intended function of the article;

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

Justification

Same as amendment 1.

Amendment 3
Article 6, paragraph 3

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

Justification

Same as amendment 1.

Amendment 4
Article 6, paragraph 4

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

notified in accordance with paragraph 3.

Justification

Same as amendment 1.

Amendment 5
Article 6, paragraphs 5

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

Justification

This ensures consistency with amendments 2, 3, and 4.

Amendment 6
Article 6, paragraphs 6

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

Justification

This ensures consistency with amendments 2, 3, and 4.

Amendment 7
Article 6, paragraphs 7

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

Justification

This ensures consistency with amendments 2, 3, and 4.

III. EVALUATION

Under the Commission's draft proposal, there are three forms of evaluation:

- **Dossier Evaluation (testing proposals):** this is compulsory for all chemicals above 100 tonnes per annum, and involves an examination of the testing proposals for the provision of information in Annexes VII and VIII;
- **Dossier Evaluation (compliance check):** this is voluntary for Member State authorities, and involves checking the accuracy of the registration dossier, and whether it fulfils the legal requirements;
- **Substance Evaluation**: the Agency and Member States will create a rolling plan of substances to be evaluated in more depth, with prioritisation so that the worst chemicals are examined first. In some cases such an evaluation will lead to further action, for example authorisation or restrictions.

Key improvements of these provisions are needed as follows:

- Perform **random spot-checks of dossiers** to ensure that dossiers are of a general high quality (new Article 40 (3a));

- Require Member States to carry out a **minimum annual number of evaluations** of the safety data and assessments provided by industry on chemicals (Article 43 a);

- **Ensure Member State participation** and a rapid response to new information (Article 43a bis);

- **Reduce the burden of evidence needed for the evaluation of intermediates** (Article 47);

- Ensure that all **Member State activities on evaluation are properly reported** (Article 51).

Amendment 1
Article 40, paragraph 3a (new)

In order to ensure that registration dossiers are being compiled in accordance with this legislation, a certain percentage of dossiers, not less than 5%, selected at random, will be subject to dossier evaluation. The Agency will select such dossiers, and distribute them equitably amongst Member States Competent Authorities, who shall then perform a compliance check as specified in this article, with verification of both paragraph 1(a) and 1(b). Any lessons learnt from this random evaluation (or from other dossier evaluations) should be communicated to the Agency on at least an annual basis, to assist in improving the quality of future registration dossiers.

Justification

It is important to ensure a minimum amount of random dossier evaluation in order to maximise the quality of submitted dossiers.

Amendment 2
Article 43 a

In order to provide a harmonised approach, the Agency shall develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria for evaluation shall include consideration of hazard data, exposure data and tonnage bands. The Agency shall take a decision on the criteria for the prioritisation of substances for further evaluation. Member States shall use these criteria for preparing their rolling plans.	In order to provide a harmonised approach, the Agency shall develop criteria for prioritising substances with a view to further evaluation. Prioritisation shall be on a risk-based approach. The criteria for evaluation shall include consideration of hazard data, exposure data and tonnage bands. The Agency shall take a decision on the criteria for the prioritisation of substances for further evaluation. Member States shall use these criteria for preparing their rolling plans. ***The Agency shall also determine a minimum number of substance evaluations that should be performed per annum in order to assist in the identification of substances requiring further examination or action. The Agency shall use this minimum figure to calculate an appropriate baseline workload for each Member State. Each Member State shall carry out, at a minimum, this number of substance evaluation.***

Justification

This will require Member States to carry out a minimum annual number of evaluations of the safety data and assessments provided by industry on chemicals. This would enhance the quality control, the prioritisation and the review of problematic substances, and would also ensure that the Member States' authorities have resources for this important work.

Amendment 3
Article 43 a bis, indent 6a (new)

A Member State may at any time add new substance(s) to their rolling plan should information emerge which leads to a concern regarding risk to human health and the environment. They must notify the Agency of their intention to add the substance to their rolling plan. Should more than one Member State notify the Agency regarding the same substance, the first Member State to notify the Agency should be appointed to evaluate the substance.

Justification

To ensure that Member States can decide to do a substance evaluation if new information emerges, whether the substance is on their rolling plan or not.

Amendment 4
Article 47

For on-site isolated intermediates, neither dossier nor substance evaluation shall apply. However, where ***a risk equivalent to the level of concern arising from the use of substances to be included in Annex XIII under Article 54 can be demonstrated arising*** from the use of an on-site isolated intermediate, the competent authority of the Member State in whose territory the site is located may:	For on-site isolated intermediates, neither dossier nor substance evaluation shall apply. However, where ***a Member State competent authority can present evidence indicating that there is an inadequately controlled risk*** arising from the use of an on-site isolated intermediate, the competent authority of the Member State in whose territory the site is located may:

Justification

The Commission text requires a very high burden of evidence on a Member State before they are allowed to ask for more information on the safety of intermediates; this amendment reduces this burden.

Amendment 5
Article 51

By 28 February of each year, each Member State shall report to the Agency on the progress made over the previous calendar year towards discharging the obligations incumbent upon the competent authorities within that State in relation to ***the examination of testing proposals***. The Agency shall publish this information on its web-site without delay.	By 28 February of each year, each Member State shall report to the Agency on the progress made over the previous calendar year towards discharging the obligations incumbent upon the competent authorities within that State in relation to ***evaluation of dossiers and substances***. The Agency shall publish this information on its web-site without delay.

Justification

To ensure that all Member State activities on evaluation are properly reported.

IV. AUTHORISATION

Authorisation is a procedure within REACH which does not have a direct equivalent in existing European chemicals legislation. It is intended to provide an effective way of regulating the use of chemicals of very high concern.

We believe it should be designed as an efficient tool to foster innovation and the search for safer alternatives. Thus the continued use of this group of substances should only be authorised when no safer alternative is available, when the socio-economic benefits outweigh the risk to human health and the environment, and when exposure and losses to the environment are minimised.

In the authorisation process laid out in the Commission's proposal, not all chemicals of very high concern will enter authorisation immediately. There will first be a phase of identification of those chemicals of most concern involving the Agency and a consultation procedure. Then, those chemicals will be prioritised to enter the full authorisation process. A deadline will be set by when use of the chemical must cease. Nevertheless, industry can apply for the continued use of a substance. An authorisation can be granted if industry successfully proves that the chemical in question will be used under 'adequate control' (Article 57.2), or that socio-economic factors outweigh the risk emanating from the substances and that safer alternatives are not yet available. We believe that, as long as this 'adequate control' route is open, the regulator cannot fully consider the availability of safer alternatives. Therefore, several improvements to the Commission's proposal are needed to ensure that an effective and workable authorisation system is in place to contribute to a high level of protection of human health and the environment.

The key improvements needed are as follows:

- **To ensure that the regulator is always able to consider the availability of safer alternatives, the criteria for granting an authorisation need to be modified**. The 'adequate control' route should be deleted. Moreover, if an authorisation is needed, it should always be temporary and include a review clause (Recital 12, Article 52, Article 55 (1) (d), Article 57 (2) (3), (6) and (7), Article 58 (1), Article 59 (4) and (5));

- **A mechanism to get early and transparent identification of chemicals that meet the criteria for authorisation should be laid out.** We suggest the creation of a candidate list for chemicals identified as substances of very high concern. This will increase the transparency of the process for all interested parties including industry. Industry could use this as an early warning system and could start to look for alternatives (new Article 53 bis, Article 55 (1), Article 55 (3), Article 56 (1) and (7));

- **The Agency should always be able to gather useful information on alternatives, while considering authorisation applications.** This will ensure that decision making is based on the best information available. This can be achieved by enabling the Agency to commission independent studies (Article 61 (3), Article 72 (1) (c));

- **The criteria for adding 'chemicals of equivalent concern" should be modified.** The current wording suggests that they must cause serious and irreversible effects to humans or the environment, which is likely to take a long time to prove, in total contradiction with a precautionary approach. Moreover, it does not appear to enable multiple exposures to be taken into account (Article 54 (f));

- **Exemptions need to be kept to the minimum** to enable the full evaluation of chemicals of very high concern (Article 53 (1), (5) and (6), Article 55 (1) (e), Article 55 (2), Article 55(4) (b), Article 59 (6)).

Amendment 1
Recital 12

The authorisation provisions provides 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 uses is adequately controlled or*** the use can be justified for socio-economic reasons.	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 ***no suitable alternatives or technologies are available and*** the use can be justified for socio-economic reasons.

Justification

This recital should reassert the objective of the authorisation procedure. The authorisation requirement will only be capable of providing the high level of protection required if it replaces substances of very high concern with suitable alternative substances or technologies wherever this is possible. To retain the alternative aim of 'adequate control' of risks is to endorse continued use and release of substances of very high concern to the environment, irrespective of the socio-economic benefits or otherwise from such uses and irrespective of whether safer alternatives are available.

Amendment 2
Article 52

The aim of this Title is to ensure ***the good functioning of the internal market while assuring that the risks from substances of very high concern are properly controlled or that these substances are replaced by suitable alternative substances or technologies.***	The aim of this Title is to ensure ***that substances of very high concern are replaced by suitable alternative substances or technologies where available, or that such alternatives are developed.***

Justification

The aim of ensuring the good functioning of the internal market is an aim which runs through all EU legislation and which is not specific to this, or any other, article within this regulation.

The aim of authorisation relates to the protection of health and the environment rather than the functioning of the internal market.

The authorisation requirement will only be capable of providing the high level of protection required if it aims to replace substances of very high concern with suitable alternative substances or technologies wherever this is possible. To retain the alternative aim of "proper control" of risks is to endorse continued use and release of substances of very high concern to the environment, irrespective of the socio-economic benefits or otherwise from such uses and irrespective of whether safer alternatives are available.

Amendment 3
Article 53, paragraph 1 (b)

(b) the use(s) of that substance on its own, in a preparation or the incorporation of the substance into an article for which the substance is placed on the market or for which he uses the substance himself has been exempted from the authorisation requirement in Annex XIII itself in accordance with Article 55(2);	***deleted***

Justification

This ensures consistence with our amendment 12 to delete blank exemptions .

Amendment 4
Article 53, paragraph 5

Paragraphs 1 and 2 shall not apply to the following uses of substances:	Paragraphs 1 and 2 shall not apply to the following uses of substances:
(a) uses in plant protection products within the scope of Directive 91/414/EEC;	(a) uses in plant protection products within the scope of Directive 91/414/EEC;
(b) uses in biocidal products within the scope of Directive 98/8/EC;	(b) uses in biocidal products within the scope of Directive 98/8/EC;
(c) uses as medicinal products for human or veterinary use within the scope of Regulation (EEC) No 2309/93 and Directives 2001/82/EC and 2001/83/EC;	(c) uses as medicinal products for human or veterinary use within the scope of Regulation (EEC) No 2309/93 and Directives 2001/82/EC and 2001/83/EC;
(d) uses as food additives within the scope of Directive 89/107/EEC;	(d) uses as food additives within the scope of Directive 89/107/EEC;
(e) uses as additives in animal feeding stuffs within the scope of Directive 70/524/EEC;	(e) uses as additives in animal feeding stuffs within the scope of Directive 70/524/EEC;
(f) uses as flavourings in foodstuffs within the scope of Decision 1999/217/EC;	(f) uses as flavourings in foodstuffs within the scope of Decision 1999/217/EC;
(g) uses as an on-site isolated intermediate or as a transported isolated intermediate;	(g) uses as an on-site isolated intermediate or as a transported isolated intermediate;
(h) use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council 48;	(h) use as motor fuels covered by Directive 98/70/EC of the European Parliament and of the Council 48;
(i) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.	(i) uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems.
	Insofar these measures provide at least as stringent controls as laid out under Title VII.

Justification

It is important to consider a wide range of uses of the chemicals concerned, in particular covering those pieces of legislation that do not examine the environmental impacts of substances, but also covering other possible sources of release and exposure. For instance, the clause which renders isolated intermediates unable to be brought under authorisation should be removed, as emissions during transport on or off site may be very significant (Article 53(5)(g)).

Amendment 5
Article 53, paragraph 6

In the case of substances that are subject to authorisation only because they meet the criteria in Article 54(a), (b) and (c) or because they are identified in accordance with Article 54(f) only because of hazards to human health, paragraphs 1 and 2 of this Article shall not apply to the following uses:	***deleted***
(a) uses in cosmetic products within the scope of Directive 76/768/EEC;	
(b) ***uses in food contact materials within the scope of Directive 89/109/EEC.***	

Justification

Blanket exemptions from the authorisation procedure should not be allowed, because allowing de facto exemptions is, in effect, to allow authorisation without any case-specific evaluation of the benefits or drawbacks of such exempted uses, or of potential alternatives. This removes two vital elements that the authorisation requirement was intended to introduce, namely transparency of decision-making and justification for allowing continued use. If there were valid reasons for a particular use, or category of use, of a substance to be "exempted", then surely these reasons would be substantive enough for these uses to pass through the full scrutiny of the authorisation process and receive authorisation. In such a case, authorisation could surely be very swiftly dealt with.

Amendment 6
Article 53 bis (new)

	Annex XIII shall contain a list of substances that are subject to authorisation; the list in Annex XIII(a) shall be a candidate list, pending the procedure for authorisation. Once the authorisation procedure being initiated, the substances shall be listed in Annex XIII(b), according to the procedure of article 55(1).

Justification

In order to stimulate voluntary measures by downstream users, and the innovation of safer alternatives, we propose that all chemicals which are agreed to meet the authorisation criteria, should be immediately listed in a candidate list for authorisation (Annex XIII (a)).

Then, on the instigation of a Member State or after consideration of the Agency's priority list, chemicals would be progressed to Annex XIIIb, when sunset dates and deadlines for applications for authorisation would be set. This will also increase the transparency of the inclusion procedure.

Amendment 7
Article 54 (f)

Substances to be included in ***Annex XIII***	Substances to be included in ***Annex XIII(a)***
The following substances ***may*** be included in Annex XIII in accordance with the procedure laid down in Article 55:	The following substances ***shall*** be included in Annex XIII***a*** in accordance with the procedure laid down in Article ***56 unless if subject to restriction(s) under Article 65***:
(f) substances, such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) and (e) and which are identified as ***causing serious and irreversible effects to humans or the environment which are equivalent to those of*** other substances listed in points (a) to (e) on a case-by-case basis in accordance with the procedure set out in Article 56;	(f) substances, such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) and (e) and which are identified as ***giving rise to a similar level of concern as*** other substances listed in points (a) to (e) on a case-by-case basis in accordance with the procedure set out in Article 56;

Justification

We believe the current wording of Article 54 (f) implies a very high burden of proof, which requires the need to show that the chemical proposed for authorisation under these circumstances is actually causing serious and irreversible effects. This will mean that pre-emptive action cannot be taken on a chemical that is accumulating in the environment and which might reach a level of concern in the future.

Amendment 8
Article 55, paragraph 1

Inclusion of substances in ***Annex XIII***	Inclusion of substances in ***Annex XIII(b)***
Whenever a decision is taken to include in ***Annex XIII*** substances referred to in Article 54**,** such a decision shall be taken in accordance with the procedure referred to in Article 130(3).	Whenever a decision is taken to include in ***Annex XIII(b)*** substances referred to in Article 54**,** such a decision shall be taken in accordance with the procedure referred to in Article 130(3).

Justification

Due to the inclusion of our candidate list, the original Commission's proposed Annex XIII becomes Annex XIII(b).

Amendment 9
Article 55, paragraph 1, point (ba) (new)

	(ba) restrictions according to Article 65;

Justification

As we believe the authorisation procedure should not exclude further restrictions (Title VIII) if necessary, it seems important that decisions to include substances in the authorisation process clearly state any restriction already set up.

Amendment 10
Article 55, paragraph 1, point (d)

(d) review periods for ***certain*** uses, ***if appropriate;***	(d) review periods for ***all*** uses, ***which shall not exceed 5 years;***

Justification

It is reasonable that all authorisations issued be temporary, because periodic review will allow (and encourage) adaptation to technical progress (e.g. consideration of new information on hazards, exposure, socio-economic benefits and availability of alternatives). All authorisations should be time-limited, and subject to review at most every 5 years depending on the state of development of safer alternatives or technologies. Without regular review periods, the momentum for the innovation of safer alternatives will be lost.

Amendment 11
Article 55, paragraph 1, point (e)

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

Justification

This ensures consistency with our proposal to avoid exemptions.

Amendment 12
Article 55, paragraph 2

Uses or categories of uses may be exempted from the authorisation requirement. In the establishment of such exemptions, account shall be taken, in particular, of the following:	***deleted***
(a) Existing specific Community legislation imposing minimum requirements relating to the protection of health or	

the environment for the use of the substance, such as binding occupational exposure limits, emission limits and so forth;

(b) Existing legal obligations to take appropriate technical and management measures to ensure compliance with any relevant health, safety and environmental standards in relation to the use of the substance.

Exemptions may be subject to conditions.

Justification

Same as amendment 5.

Amendment 13
Article 55, paragraph 3

Prior to a decision to include substances in Annex XIII*, t**he Agency shall recommend priority substances to be included specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with: (a) PBT or vPvB properties; (b) wide dispersive use; or (c) high volumes. ***The number of substances included in Annex XIII and the dates specified under paragraph 1 shall also take account of the Agency's capacity to handle applications in the time provided for.	***T***he Agency shall recommend priority substances to be transferred ***from Annex XIII(a) to Annex XIII(b)*** specifying for each substance the items set out in paragraph 1. Priority shall normally be given to substances with: (d) PBT or vPvB properties; (e) wide dispersive use; or (f) high volumes.

Justification

This ensures consistency with our proposal for a new article 53 bis (amendment 16).

Amendment 14
Article 55, paragraph 4, point (b)

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

Justification

Same as amendment 5.

Amendment 15
Article 55, paragraph 5

After inclusion of a substance in Annex XIII, this substance shall not be subject to new restrictions under the procedure outlined in Title VIII covering the risks to human health or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIII.	***deleted***

Justification

The authorisation procedure should not exclude further restrictions (used as a safety net for the whole system) if necessary, especially when new scientific information on very high concern chemicals emerge and quick action is needed..

Amendment 16
Article 56, paragraph 1

Identification of substances referred to in Article 54 ***(d), (e) and (f).***	Identification ***and inclusion in Annex XIII(a)*** of substances referred to in Article 54.
To identify substances referred to in Article 54(d), (e), and (f), the procedure set out in paragraphs 2 to 7 of this Article shall apply prior to any recommendations under Article 55(3).	***1. Substances referred to in Article 54 (a) (b) and (c) shall be included in Annex XIIIa.***
	1a. Substances referred to in Article 54(d), (e), and (f), shall be included in Annex XIIIa as a result of the identification procedure set out in paragraphs 2 to 7 of this Article.
	1b. Substances which are identified as priority hazardous substances in Annex X of Directive 2000/60/EC shall be included in Annex XIIIa.
	1c. Substances which are identified as chemicals for priority action in Annex 7 of the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic, and all relevant international agreement shall be included in Annex XIIIa.
	1d. The period for inclusion shall be 3 months after identification or implementation of this Regulation.

Justification

The proposal as it stands does not provide any timeline for identifying and bringing chemicals meeting the criteria for authorisation under the procedure.

Moreover, the authorisation provisions should provide a tool to meet commitments under the Water Framework directive and the OSPAR Convention for the Protection of the Marine Environment of the North-East Atlantic.

Amendment 17
Article 56, paragraph 7

If, within 30 days of referral, the Member State Committee reaches a ***unanimous*** agreement ***on the identification***, the Agency ***may*** include that substance in its recommendations under Article 55(3)**.** If the Member State Committee fails to reach a ***unanimous*** agreement, it shall adopt an opinion within 30 days of referral. The Agency shall transmit that opinion to the Commission, including information on any minority view within the Committee.	If, within 30 days of referral, the Member State Committee reaches a ***qualified majority*** agreement ***that the substance meets the criteria for authorisation and should be included in Annex XIII(b),*** the Agency ***within 15 working days shall recommend to the Commission the inclusion of the substance in Annex XIII(b) as stated in article 55.3.*** If the Member State Committee fails to reach a ***qualified majo***rity agreement, it shall adopt an opinion within 30 days of referral. The Agency shall transmit that opinion to the Commission ***within 15 working days*****,** including information on any minority view within the Committee.

Justification

A *Deadline should be introduced in order to avoid blockage at the level of the Agency.*

Amendment 18
Article 57, paragraph 2

An authorisation shall be granted if the risk to human health or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII is adequately controlled in accordance with Annex I, section 6, and as documented in the applicant's chemical safety report.	***deleted***
The Commission shall not consider the following:	
(a)risks to human health and the environment of emissions of the substance from an installation for which a permit was granted in accordance with Council Directive 96/61/EC 49 ;	

(b) risks to and via the aquatic environment of discharges of the substance from a point source governed by the requirement for prior regulation referred to in Article 11(3) and legislation adopted under Article 16 of Directive 2000/60/EC of the European Parliament and of the Council 50;

(c) risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC 51, Council Directive 93/42/EEC52 or Directive 98/79/EC of the European Parliament and of the Council.

Justification

The authorisation requirement will only be capable of providing the high level of protection required if it is aiming at replacing substances of very high concern with suitable alternative substances or technologies wherever this is possible. To retain the alternative aim of "adequate control" of risks is to endorse continued use and release of substances of very high concern to the environment, irrespective of the socio-economic benefits or otherwise from such uses and irrespective of whether safer alternatives are available.

Amendment 19
Article 57, 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:	***A***n 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**, *and if measures to minimise exposure and discharges, emissions and losses to the environment are put in place*.** This decision shall be taken after consideration of all of the following elements:
(a) the risk posed by the uses of the substance;	(a) the risk posed by the uses of the substance;
(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;	(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;
(c) the analysis of the alternatives submitted by the applicant under Article 59(5) and any third party contributions submitted under Article 61(2);	(c) the analysis of the alternatives submitted by the applicant under Article 59(5) and any third party contributions submitted under Article 61(2);

(d) available information on the health or environmental risks of any alternative substances or technologies.	(d) available information on the health or environmental risks of any alternative substances or technologies.

Justification

It is important to ensure that all applications for authorisation, which only applies to substances of very high concern, are processed through 57(3), allowing the regulator to always consider the socio-economic justification and the availability of safer alternatives. Authorisations should only be granted when there is no safer alternative, an overwhelming societal need for the chemical exists, and measures to minimise exposure and losses to the environment are in place. The availability of a safer alternative alone should therefore be grounds to refuse authorisation.

Amendment 20
Article 57 , paragraph 6

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

Justification

Same as amendment 10.

Amendment 21
Article 57, paragraph 7

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

Justification

Same as amendment 10.

Amendment 22
Article 58, paragraph 1

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

Justification

Same as amendment 19.

Amendment 23
Article 59, paragraph 4 (da) (db) (new)

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

Justification

This ensures consistency with the requirements of our amendments for article 57, and to ensure that substitution plans are produced for all applications for authorisation to stimulate innovation towards safer alternatives.

Amendment 24
Article 59, paragraph 5

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

Justification

This is to be consistent with amendment 23.

Amendment 25
Article 59, paragraph 6

The application shall not include any of the following:	***deleted***
(a) the risks to human health and the environment of emissions of the substance from an installation for which a permit has been granted in accordance with Directive 96/61/EC;	
(b) the risks to and via the aquatic environment of discharges of the substance from a point source governed by the requirement for prior regulation referred to in Article 11 (3) and legislation adopted under Article 16 of Directive 2000/60/EC;	
(c) the risks to human health arising from the use of a substance in a medical device regulated by Directive 90/385/EEC, 93/42/EEC or 98/79/EC.	

Justification

It is important to consider a wide range of uses of the chemicals concerned, in particular covering those pieces of legislation that do not examine the environmental impacts of substances, but also covering other possible sources of release and exposure.

Regulation by emission limit values is not a suitable means for dealing with chemicals of very high concern and cannot ensure a high degree of protection for human health and the environment, particularly PBT and vPvB substances. It is important that authorisation applications do consider the risks in full to human health and the environment, even where emission limits exist.

Amendment 26
Article 61, paragraph 3

In preparing its opinion, each Committee referred to in paragraph 1 shall first check that the application includes all the information specified in Article 59 that is relevant to its remit. If necessary, a Committee shall ask the applicant for additional information to bring the application into conformity with the requirements of Article 59. Each Committee shall also take into account any information submitted by third parties.	In preparing its opinion, each Committee referred to in paragraph 1 shall first check that the application includes all the information specified in Article 59 that is relevant to its remit. If necessary, a Committee shall ask the applicant for additional information to bring the application into conformity with the requirements of Article 59. Each Committee shall also take into account any information submitted by third parties**,** ***and may ask these third parties for further information, if required.*** ***If either or both committees decide that additional information is needed on alternative substances or technologies, then they may commission a consultant or Member State authority to carry out a time-limited investigation into available alternatives. Such investigations will be funded by the authorisation fee set by the Agency (Article 59 (7)).***

Justification

Concern has been expressed about the difficulty of making decisions about the availability of safer alternatives within the Agency committees. In our view it is crucial to allow the Agency committees more flexibility in information gathering, so that, where appropriate, a committee could commission independent consultants (or experts from Member States) to report on potential substitutes. This additional information would then be available for use by the Agency committees when they decide the merits of an application for authorisation. It must be remembered that Member States experts are already having to make decisions on availability of safer alternatives within the current existing chemicals regulatory system, for example when deciding to restrict the flame retardants penta and octa-BDE. The Agency committees already have 10 months in which to draft their decision, so it should be possible to complete a study into alternatives within this time period, such that there is no need to change any of the timelines proposed in the Commission's text.

Amendment 27
Article 62

Obligation of holders of authorisations	***Information obligations for substances subject to authorisation***
Holders of an authorisation shall include	***All substances or preparations meeting the***

the authorisation number on the label before they place the substance on the market for an authorised use.	***criteria of Article 54 and articles containing such substances or preparations shall be labelled and be accompanied, at any time, by a safety data sheet. The label shall include (a) the name of the substance, (b) the fact that the substance comes under Annex XIII and (c) any particular use for which the substance has been authorised.***

Justification

The proposed obligations of holders of authorisations are not sufficient to raise the necessary awareness of everyone in the whole supply chain. It is essential that the many users of chemicals in the manufacturing and the supply chain as well as those consuming articles and managing waste are able to obtain crucial information on the environmental and adverse health effects of chemicals of very high concern that are subject to authorisation.

Amendment 28
Article 72, paragraph 1 (c)

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

Justification

This reinforces our proposal that decision-making under the authorisation provisions shall always take into account the availability of safer alternatives.

V. AGENCY RESPONSIBILITIES

The REACH system should not be further centralised. The Agency will already be able to ensure harmonisation of evaluation procedures across Member States, and further centralisation of this process will endanger the development and retention of Member State competence in chemicals assessment, and create a risk that the quality of decision making will be affected. Member State expertise will be essential for assisting businesses with REACH implementation and in enforcing the REACH system.

On the other hand, the current text would enable the Risk Assessment and Socio-Economic Analysis Committees to become disconnected from the national regulators. This could lead to difficulties in getting acceptance of the committees' conclusions by the Member States Committee, which could thus delay the regulatory decision-making. Moreover, there is a need to make sure these committees will also be able to assess safer alternatives for very high concern chemicals.

The key improvements needed are as follows:

- **Empower the risk assessment committee to become a committee for assessing the risks and alternatives** (Article 72 (1) (c));

- **Add a deadline for the publication of information** (Article 73 (2) (d));

- **Ensure effective Member State participation in Committees** (Article 81 (1) and (2)).

Amendment 1
Article 72, paragraph 1 (c)

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

Justification

This reinforces our proposal that decision-making under the authorisation provisions shall always take into account the availability of safer alternatives.

Amendment 2
Article 73, paragraph 2 (d)

(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 all non-confidential information in the data base(s) publicly available over the Internet, including a short profile of the hazardous properties, labelling requirements and relevant Community legislation, including authorised uses and restriction measures;	(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 all non-confidential information in the data base(s) publicly available over the Internet ***as soon as possible and in any case within 30 days of receipt***, including a short profile of the hazardous properties, ***the chemical safety report,*** labelling requirements and relevant Community legislation, including authorised uses and restriction measures;

Justification

The current text does not give the Agency a deadline to publish information on the public database, which could allow information not to enter the public domain due to delays.

Amendment 3
Article 81, paragraph 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***	Each Member State ***shall appoint one member to the committe for assessment of risks and alternatives***. Members shall be appointed for their role and experience in the regulation of chemicals and/or for their technical and scientific expertise in

appoint the members of the Committee from this list, including at least one Member State that has nominated candidates. Members shall be appointed for their role and experience in the regulation of chemicals and/or for their technical and scientific expertise in reviewing risk assessments of substances.	reviewing risk assessments of substances.

Justification

This ensures effective Member States participation in Committees.

Amendment 4
Article 81, paragraph 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 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.	Each Member State ***shall appoint one member to the*** Socio-economic Analysis committee. Members shall be appointed for their role and experience in the regulation of chemicals and/or for their expertise in socio-economic analysis.

Justification

This ensures effective Member States participation in Committees.

VI. CLASSIFICATION AND LABELLING

The system of classification and labelling of chemicals is vital for many other pieces of legislation, including worker safety, chemical transport and accidents. It is therefore essential that REACH does not reduce the level of protection in this area.

Amendment 1
Article 110, paragraph 3

When this obligation results in different entries on the inventory for the same substance, the ***notifiers and the registrants shall make every effort to come to an agreed entry***.	When this obligation results in different entries on the inventory for the same substance, the ***Agency shall determine the information to be included in the inventory.***

Justification

The authorities should have the final decision if industry disagrees, to ensure that the classification and labelling inventory is as usable as possible.

Amendment 2
Article 112, paragraph 1

Harmonised classification and labelling at the Community level ***shall,*** from the entry into force of this Regulation, ***only*** be added to Annex 1 of Directive 67/548/EEC ***for classification of a substance as carcinogenic, mutagenic or toxic for reproduction categories 1, 2, or 3, or as a respiratory sensitiser.*** To this end, Member State competent authorities may submit proposals to the Agency for harmonised classification and labelling in accordance with Annex XIV.	Harmonised classification and labelling at the Community level ***may*** from the entry into force of this Regulation ***also*** be added to Annex 1 of Directive 67/548/EEC ***as well as to Directive 1999/45/EC.*** To this end, Member State competent authorities may submit proposals to the Agency for harmonised classification and labelling in accordance with Annex XIV.

Justification

There is no reason to limit the possibilities for authorities to do harmonised classifications of substances on a case by case basis. Moreover, the Classification of preparations determines whether a chemical safety assessment must be made (article 29), so it is important that authorities have a possibility to check these classifications. Otherwise dangerous substances in volumes up to 30 % may be passed on to downstream users as ingredients in preparations without information to downstream users about their presence and without authorities being able to check if the classification is ok.

VII. RIGHT TO KNOW AMENDMENTS

In order for REACH to be effective and to comply with binding international conventions and Community legislation, it has to ensure transparency and access to information for everyone. This is essential to ensure that everyone has access to information on the chemicals they are handling and which are in articles they buy. Moreover, increased transparency will allow for monitoring the effectiveness of the regulatory system. The Community also needs to fully implement the requirements on access to environmental information of the Aarhus Convention, to which the Community is a signatory. The proposal, as it stands now, is not in conformity with the provisions of the Convention.

The key improvements needed are as follows:

- **Information on chemicals in articles should be available to all users, retailers and consumers.** Under REACH, information on substances and preparations stops being available as soon as a chemical enters in an article. However, we believe that all downstream users of articles containing chemicals (including retailers) should be granted access to information regarding these chemicals. To this end, companies incorporating substances and preparations in articles and the subsequent suppliers of those articles or derivatives thereof should be obliged to pass on information on the chemicals contained in the products they sell to their customers. We propose that safety data sheets are passed along the supply chain to retailers. Customers may request to see these (new Article 31 bis);

- **Articles which contain chemicals of very high concern should be labelled.** All downstream users will then be aware of their use (and disposal) of such chemicals and may be able to find substitutes or alternative procedures (Article 62);

- **Data should be entered onto the centrally maintained (public) database within 15 days of receipt.** Currently there is no time limit; swift data entry will facilitate access to that information, avoiding the need for individual requests as far as possible (Article 73 (2) (d), Article 73 (2) (e), Article 115 (1));

- **The procedure for access to information must be clarified and streamlined to be consistent with the Aarhus Convention.** In the current text of the proposal, the procedure to access information held by the Agency or Member States is extremely cumbersome and gives industry considerable rights to block release of information, inevitably causing what would be unlawful delays even if the information is eventually released.The grounds for withholding information are weaker than those in the Aarhus Convention, although it should be noted that the Convention does recognise the protection of legitimate commercial interests. If industry wants information to be treated as confidential it should provide full justification (as is already established in existing Community legislation, such as Regulation 793/93/EEC and Directive 92/32/EEC) and show that release of information would adversely affect its interests. The public interest in disclosure of information should also be taken into account (new Article 9 (ba), Article 115 (2) and (3);

- **The list of 'never confidential' information should be extended to include the full registration dossier, the chemical safety report, information on production and import volumes, and most importantly the name of the registrant.** The list included in the proposal is not sufficient, since it does not provide downstream users, retailers and the general public with all the necessary information that they might require to make their own judgements about risks and alternatives. Public access to all toxicity, fate, exposure, use

categories and risk assessment data should be ensured. Moreover, both the current Existing Substances Regulation (793/93/EEC) and Notification of New Substances Directive (93/32/EEC) specifically state that the name of the manufacturer or importer/notifier is never to be confidential, whereas this could be the case under the REACH proposal. This is unacceptable - REACH cannot be more restrictive than existing legislation (Article 116 (1));

- **The list of 'always confidential' information should not include information which may be significant for environmental protection.** This would not be in line with the Aarhus Convention. A decision to withhold such information should always be subject to a test of the public interest in its disclosure (Article 116 (2)).

Amendment 1
Article 9 (ba) (new)

(ba) When submitting information for registration purposes under (a) and (b) the applicant may ask that specifically designated documents or parts of documents are treated confidentially. The applicant shall provide full justification for any such requests. The authority receiving the information shall decide which information shall be kept confidential.

Justification

Existing legislation (Regulation 793/93/EEC and Directive 92/32/EEC) is similar with respect to the burden on industry to justify confidentiality: a manufacturer can indicate commercially sensitive information but this must be accompanied by a full justification. The authority receiving the information shall decide on its own responsibility which information is covered.

Amendment 2
Article 31 bis (new)
Duty to communicate information on substances in articles

Downstream users who incorporate into an article a substance or preparation for which a safety data sheet was established, and those who subsequently handle or further process that article, shall pass on the safety data sheet to any recipient of the article or its derivative. A consumer is not a recipient.

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

Justification

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

Amendment 3
Article 62

Obligation of holders of authorisations	***Information obligations for substances subject to authorisations***
Holders of an authorisation shall include the authorisation number on the label before they place the substance on the market for an authorised use.	***All substances or preparations meeting the criteria of Article 54 and articles containing such substances or preparations shall be labelled and be accompanied, at any time, by a safety data sheet. The label shall include (a) the name of the substance, (b) the fact that the substance comes under Annex XIII and (c) any particular use for which the substance has been authorised.***

Justification

The proposed obligations of holders of authorisations are not sufficient to raise the necessary awareness of everyone in the whole supply chain. It is essential that the many users of chemicals in the manufacturing and the supply chain as well as those consuming articles and managing waste are able to obtain crucial information on the environmental and adverse health effects of chemicals of very high concern that are subject to authorisation.

Amendment 4
Article 73, paragraph 2 (d)

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) 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 information identified in Article 116(1) in the data base(s) publicly available over the *Internet* ***within 15 working days***, and making information in the databases available on request ***in accordance with Article 115 (2);***

Justification

A time line for entry of (public) information into the database(s) is necessary otherwise the Agency could almost indefinitely postpone this task, particularly if resources are low. This would not be efficient in any case, because there is nothing to stop a citizen requesting the information directly before it is entered onto the database. We propose 15 working days on the basis that if one requested the information then Regulation 1049/2001 sets this as the standard response time.

Amendment 5
Article 73, paragraph 2 (e)

(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) making publicly available information as to which substances are being, and have been evaluated ***within 15 working*** days of receipt of the information at the Agency, in accordance with Article 116(1);

Justification

Article 73(2)(e) establishes the Agency's duty to make publicly available information on evaluation of substances within 90 days. This is not in accord with the benchmark set in the Aarhus Convention and Regulation 1049/2001 for responding to requests. If one asked the Agency for a document then they would normally have to respond within 15 working days under Regulation 1049/2001.

Amendment 6
Article 115, paragraph 1

Access to ***non-confidential*** information submitted in accordance with this Regulation shall be granted for documents held by the Agency in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council. The Agency shall make such information available on request, in accordance with Article 73(2)(d).	Access to information submitted in accordance with this Regulation shall be granted for documents held by the Agency in accordance with Regulation (EC) No 1049/2001 of the European Parliament and of the Council. The Agency shall make such information ***publicly*** available ***on its website and*** on request, in accordance with Article 73(2)(d).

Justification

This will ensure that basic information about chemicals is made available promptly to business and the general public (where there is no genuine reason for confidentiality).

Amendment 7
Article 115, paragraph 2

Whenever a request for access to documents is made under Regulation (EC) No 1049/2001 to the Agency, the Agency shall perform the consultation of the third party provided for in Article 4(4) of Regulation (EC) No 1049/2001 in accordance with the second and third subparagraphs.	Whenever a request for access to documents***, not listed under Article 116 (1)***, is made under Regulation (EC) No 1049/2001 to the Agency ***for which the third party had asked for confidentiality***, the Agency shall perform the consultation of the third party provided for in Article 4(4) of Regulation (EC) No 1049/2001 in accordance with the second and third subparagraphs.
The Agency shall inform the registrant, potential registrant, downstream user, applicant or other party concerned of this	The Agency shall inform the registrant, ***and***

request. ***The party concerned may submit a declaration within 30 days identifying the information covered by the request which he considers to be commercially sensitive and disclosure of which might harm him commercially and which he therefore wishes to be kept confidential from all persons other than the competent authorities, the Agency and Commission. He shall give a justification in each case.***

Such a declaration shall be considered by the Agency, which shall decide, on the basis of the justification, whether to accept this declaration before deciding whether to grant the request for access to documents. The Agency shall inform the party concerned who may, in accordance with Articles 87, 88 and 89, appeal to the Board of Appeal against any decision ***by the Agency not to accept the declaration,*** within 15 days of that decision. Such an appeal shall have suspensive effect. The Board of Appeal shall decide on the appeal within 30 days.

as appropriate, potential registrant, downstream user, applicant or other party concerned of this request.

Within 15 working days from registration of the application, the Agency shall inform the applicant as well as the registrant, potential registrant, downstream user or other party concerned of its decision which all may, in accordance with Articles 87, 88 and 89, appeal to the Board of Appeal against any decision within 15 days of that decision. Such an appeal shall have suspensive effect. The Board of Appeal shall decide on the appeal within 30 days.

Justification

The amendment ensures that the timeline for the initial decision is compliant with the Aarhus Convention and Regulation 1049/2001. The Aarhus Convention requires information to be released within one month except in cases where the "volume and complexity of the information justify an extension of this period up to two months after the request". It also permits all parties to appeal a decision. As it stands, the text explicitly permits industry to appeal a decision to disclose information, but does not grant rights of appeal to those denied information.

Furthermore, we do not consider the test of confidentiality to be rigorously defined. Both the terms "commercially sensitive" and "which might harm him commercially" are entirely subjective and not recognised by the Aarhus Convention The mere possibility ('might') of harm is not sufficient to trigger the exception set out in Article 4(4)(d) of the Convention which requires that the disclosure actually "would adversely affect" the interest protected. The distinction is important. The question of whether the information actually is confidential is subject to objective consideration by the Courts or by an independent tribunal. Nothing in the wording of Article 115 currently requires the Agency or the Board to consider the question of whether the information actually is confidential.

It will not in every case be appropriate for the Agency to seek the views of a third party, and furthermore, the Agency is required to make the decision 'on the basis of the justification' given by the applicant under registration (see amendment 1 above). The justification given by the applicant will inevitably be one-sided. A decision made on that basis would undermine the purpose of Aarhus.

Amendment 8
Article 115, paragraph 3

Access to ***non-confidential*** information submitted in accordance with this Regulation shall be granted for documents held by competent authorities of the Member States in accordance with Directive 2003/4/EC of the European Parliament and of the Council. ***Member States shall ensure that a system is established under which any party concerned may appeal with suspensive effect against decisions taken in relation to access to documents.***	Access to information submitted in accordance with this Regulation shall be granted for documents held by competent authorities of the Member States in accordance with Directive 2003/4/EC of the European Parliament and of the Council.

Justification

Art. 115(3) provides that requests to Member States be dealt with in accordance with Directive 2003/4. However, that requirement is then substantially undermined by the requirement for Member States to establish a system by which a party concerned may appeal with suspensive effect against decisions taken. The effect of that will inevitably be to result in considerable and unjustified delay. It will open the door to establishment of a system in which requests for this type of information are routinely not addressed within the one month limit required in law. Again, the only way in which such a system could be sustained would be where it was impermissibly determined in advance that all requests for REACH information to Member States were of sufficient volume and complexity as to require an extension.

Amendment 9
Article 116, paragraph 1

The following information shall not be considered as confidential:	The following information shall not be considered as confidential:
(a) the trade name(s) of the substance;	(a) the trade name(s) of the substance;
(b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC;	(b) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC;
(c) if applicable, the name of the substance as given in Einecs;	(c) if applicable, the name of the substance as given in Einecs;
(d) physicochemical data concerning the substance and on pathways and environmental fate;	(d) physicochemical data concerning the substance and on pathways and environmental fate;
(e) the result of each toxicological and ecotoxicological study;	(e) the result of each toxicological and ecotoxicological study;
(f) any derived no-effect level (Dnel) or predicted no-effect concentration (Pnec)	(f) any derived no-effect level (Dnel) or predicted no-effect concentration (Pnec)

established in accordance with Annex I;	established in accordance with Annex I;
(g) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;	**(g)** if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;
(h) the guidance on safe use provided in accordance with section 4 of Annex IV;	**(h)** the guidance on safe use provided in accordance with section 4 of Annex IV;
(i) the information contained in the safety data sheet, except ***for the name of the company/undertaking or*** where the information is considered confidential by application of paragraph 2;	**(i)** the information contained in the safety data sheet, except where the information is considered confidential by application of paragraph 2;
(j) analytical methods if requested in accordance with Annex VII or VIII which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans;	(j) analytical methods if requested in accordance with Annex VII or VIII which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans;
(k) the fact that testing on vertebrate animals has been carried out.	**(k)** the fact that testing on vertebrate animals has been carried out.
	(ka)the name of the registrant;
	(kb)chemical structure(s) of the substance;
	(kc)the total volume of a substance in the EU market based on volume classes;
	(kd)use categories;
	(ke)list of ingredients in preparations;
	(kf)the Chemical Safety Report;
	(kg)the tonnage band of the substance.

Justification

The Commission's proposed procedure to access and make publicly available chemical safety information is cumbersome and ineffective. The list of 'never confidential' information is not comprehensive, so the public (as well as businesses) will still be unable to make their own judgements about risks and alternatives. There is a range of information where there is no convincing argument for how they could be considered as confidential, including the (qualitative) ingredients of preparations, total production tonnage, use categories and exposure assessments. We also note that the Aarhus Convention categorically states that" Within this framework [of confidentiality], information on emissions which is relevant for the protection of the environment shall be disclosed."

The name of the registrant is necessary in order to remove any barriers to data-sharing and enforcement, and to ensure that the public is able to see who is responsible for producing or importing a particular chemical. In any case it would seem contrary to any notion of a transparent, robust and non-corrupt system for the name of an applicant to be withheld.

Amendment 10
Article 116, paragraph 2

The following information shall be considered as confidential**, *even if no declaration in accordance with Article 115(2) is made***:	The following information shall be considered as confidential:
(a) details of the full composition of a preparation;	**(a)** details of the full composition of a preparation;
(b) the precise use, function or application of a substance or preparation;	(b) links between a manufacturer or importer and his downstream users.
(c) ***the precise tonnage of the substance or preparation manufactured or placed on the market;***	
(d) links between a manufacturer or importer and his downstream users.	

Justification

The list of 'always confidential' information should be limited as much as possible. A presumption *of confidentiality of any environmentally-relevant information would not be in accordance with the Aarhus Convention, although we recognise that manufacturers/importers can request confidentiality "in order to protect a legitimate economic interest" (Aarhus Convention, Article 4(4)(d)), but taking into account the public interest in disclosure and taking into account whether the information relates to emissions into the environment.*

VIII. CHILDREN'S AMENDMENTS

- **Children** are physiologically different from adults. The younger the child, the greater the difference. This affects the uptake of substances in the body, the distribution through tissue, metabolisation by enzymes and excretion from the body.
- **Children**, per unit of body weight, are more heavily exposed, to environmental hazards, they drink more water, eat more food, breathe more air, absorb more toxics than adults (in most cases). Young children crawl a lot and often put their hands and all kinds of objects in their mouths.
- **Children** are open to longer term risks because of early exposure, particularly before birth, or continual exposure, they have their whole lives ahead of them and may develop chronic diseases that take several decades to appear.
- **Children** are more susceptible to long-term and inter-generational effects of bio-accumulation. Toxics are stored up and passed to our children and grandchildren through the placenta and breast feeding.

The World Health Organisation (WHO) has stated that we need to establish child-focused protective policies based on better knowledge of biological susceptibility, of socio-economic and psychosocial determinants of environmental exposure to health hazards.

At present REACH does not fully:

- consider the risks, unique vulnerabilities and susceptibilities of children and include children´s exposure patterns at different times of development?
- take into account child or reproductive specific toxicity and exposure?

Please support the amendments below to ensure REACH will provide adequate protection for children in periods of heightened susceptibility during the course of their development. To ensure that the effects of chemicals involving aspects such as behaviour, learning ability, motor skills, immunity or fertility, while these are difficult to identify and are needing improvements to existing research protocols, are taken into account.

While chemical substances may produce the same types of effects in adults and children, these can occur at different exposure levels. In addition, substances can result in effects that are unique to children, and that are associated with adverse effects on the development of organs or organ systems. Effects on the development of the nervous system and the immune system may remain unnoticed. This may also apply to effects resulting from endocrine disruption. Changes which are most likely to remain unnoticed are those resulting from exposure during development that only emerge in later life.

Amendment 1
Recital 4

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

Justification

The European Parliament has previously considered that ´protecting the health of children against environment-related diseases is an essential investment with a view to ensuring adequate human and economic development´, (Report on European Environment and Health Strategy A5-0193/2004 Marit Paulsen) REACH should be seen as an opportunity not just especially protect the health of workers but also those most vulnerable to chemical exposures.

Amendment 2
Recital 5

The assessment of the operation of the four main legal instruments governing chemicals in the Community (Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (in the meantime replaced by Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the law, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations), Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances and Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations) identified a	The assessment of the operation of the four main legal instruments governing chemicals in the Community (Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (in the meantime replaced by Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the law, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations), Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances and Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations) identified a

number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field.	number of problems in the functioning of Community legislation on chemicals, resulting in disparities between the laws, regulations and administrative provisions in Member States directly affecting the functioning of the internal market in this field ***and a failure to protect public health and the environment in a precautionary manner*.**

Justification

There should be a recognition that REACH is filling the gaps in knowledge related to the protection of public health and the environment

Amendment 3
Recital 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 alternatives 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 authorities should ensure a high level of protection throughout the internal market, it is appropriate that the Commission should be the granting authority	To ensure a sufficiently high level of protection for human health***, in particular to vulnerable populations*,** 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 alternatives 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 authorities should ensure a high level of protection throughout the internal market, it is appropriate that the Commission should be the granting authority

Justification

The European Parliament has previously considered that ´protecting the health of children against environment-related diseases is an essential investment with a view to ensuring adequate human and economic development´, (Report on European Environment and Health Strategy A5-0193/2004 Marit Paulsen)

Amendment 4
Recital 89

Resources should be focused on substances	Resources should be focused on substances

of the highest concern. A substance should therefore be added to Annex I of Directive 67/548/EC ***only*** if it meets the criteria for classification as a carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, ***or*** as a respiratory sensitiser	of the highest concern. A substance should therefore be added to Annex I of Directive 67/548/EC if it meets the criteria for classification as a carcinogenic, mutagenic or toxic for reproduction categories 1, 2 or 3, as a respiratory sensitiser, ***or recognised as a possible threat to human health or the environment***

Justification

Many health endpoints have not at this present time been fully identified or do not have scientific protocols to test for non-standard effect, for example many neuro-developmental disorders. There should always be the possibility to add a substance if it is considered to be a threat to human health

Amendment 5
Article 3, point 30 (new)

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

Justification

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

Amendment 6
Article 57, point 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:	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**,** ***especially including vulnerable populations*** or the environment arising from the use of the substance and if there are no suitable alternative substances or technologies. This decision shall be taken after consideration of all of the following elements:
(a) the risk posed by the uses of the substance;	(a) the risk posed by the uses of the substance;
(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;	(b) the socio-economic benefits arising from its use and the socio-economic implications of a refusal to authorise as demonstrated by the applicant or other interested parties;

(c) the analysis of the alternatives submitted by the applicant under Article 59(5) and any third party contributions submitted under Article 61(2);	(c) the analysis of the alternatives submitted by the applicant under Article 59(5) and any third party contributions submitted under Article 61(2);
(d) available information on the health or environmental risks of any alternative substances or technologies.	(d) available information on the health or environmental risks of any alternative substances or technologies.

Justification

The European Parliament has already ´pointed out that current risk assessment methodologies do not specifically consider foetuses, infants and children and the wide range of exposure patterns that exist within this population´ under the REACH proposal (Report on European Environment and Health Strategy A5-0193/2004 Marit Paulsen). Within the Authorisation process it is essential that these vulnerable populations are taken into consideration, otherwise exposures to these pollutants of the vulnerable populations will continue

Amendment 7
Article 65, point 1

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

Justification

Citizens in the European Union understand that what they are exposed to in reality are many different mixtures of pollutants. There will always be great disparities between actual exposure and what is tested in a laboratory. However, if it is discovered that particular combinations of pollutants posse unacceptable risks then these combinations of exposure should be reduced or eliminated.

Amendment 8
Annex I, point 1.4.1

1.4.1. Based on the outcomes of steps 1 to 3, a Derived No-Effect Level(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the	1.4.1. Based on the outcomes of steps 1 to 3, a Derived No-Effect Level(s) shall be established for the substance, reflecting the likely route(s), duration and frequency of exposure. If justified by the exposure scenario(s), a single DNEL may be sufficient. However, taking into account the

available data and the exposure scenario(s) in Section 5 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. Workers, consumers and humans liable to exposure indirectly via the environment) and ***possibly*** for ***certain sub-populations (e.g. Children, pregnant women)*** and for different routes of exposure. A full justification shall be given specifying, *inter alia*, the choice of the data used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. If more than one route of exposure is likely to occur, then a DNEL shall be established for each route of exposure and for the exposure from all routes combined. When establishing the DNEL, the following factors shall, *inter alia,* be taken into account:

(i)the uncertainty arising, among other factors, from the variability in the experimental data and from intra – and inter-species variations;

(ii) the nature and severity of the effect;

(iii) the human population to which the quantitative and/or qualitative information on exposure applies.

available data and the exposure scenario(s) in Section 5 of the Chemical Safety Report it may be necessary to identify different DNELs for each relevant human population (e.g. Workers, consumers and humans liable to exposure indirectly via the environment) and for ***vulnerable populations*** and for different routes of exposure. A full justification shall be given specifying, *inter alia*, the choice of the data used, the route of exposure (oral, dermal, inhalation) and the duration and frequency of exposure to the substance for which the DNEL is valid. If more than one route of exposure is likely to occur, then a DNEL shall be established for each route of exposure and for the exposure from all routes combined. When establishing the DNEL, the following factors shall, *inter alia,* be taken into account:

(i) the uncertainty arising, among other factors, from the variability in the experimental data and from intra and inter-species variations;

(ii) the nature and severity of the effect;

(iii) the human population to which the quantitative and/or qualitative information on exposure applies.

(iv) particular susceptibilities of vulnerable populations;

(v) any indication of non-standard effects, especially where the mode of action remains unknown or insufficiently characterised;

(vi) possible co-exposures to other chemicals;

***(vii) uncertainties regarding the quality of data and overall confidence in the database*;**

Justification

The European Parliament has already ´pointed out that current risk assessment methodologies do not specifically consider foetuses, infants and children and the wide range of exposure patterns that exist within this population´ under the REACH proposal (Report on European Environment and Health Strategy A5-0193/2004 Marit Paulsen

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