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**REACH REGULATION  
PUBLIC INTERNET CONSULTATION**

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### **B - Confidentiality**

**I would like my identity to be kept confidential**

(please leave this box blank if you agree that your name and organisation will be identified on the Commission's website for public access)

### **C - SME**

**Are you a small or medium sized enterprise? ([EC legal definition](#))**  
please specify the number of members:

### **D - Description of your primary activities**

(please select only one of the following)

#### **Industry**

**Manufacturer**

**Importer**



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- Downstream user**
- Distributor**
- Trade association**
- Other**

**NGO**

- Environmental group**
- Animal welfare group**
- Trade union**
- Consumer organisation**
- Other**

**Public authorities**

- EU Member State government**
- Other national government**
- International organisation**
- National or regional authority**

**Other**

- Academic or technical institute**
- Worker in chemicals or downstream industry**
- EU citizen**
- Other**

**Please structure your response according to the following topic areas and provide comments or proposals for amendments to the legislation. Please comment on those topics that are relevant to you.**

**When finished, please send your document to the following address:**

[entr-env-ec-reach@cec.eu.int](mailto:entr-env-ec-reach@cec.eu.int).

***Thank you in advance for your contribution.***



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## **0. General Comments**

The EU needs a new regulatory system that leads to the phase out of those chemicals that accumulate in our bodies or the environment, or disrupt hormonal systems, through *inter alia* the use of safer alternatives wherever and whenever these are available. The Commission's proposals go some way towards achieving this, but have a number of crucial flaws.

### **On the positive side, we welcome:**

The **development of a new system**, and believe that the general direction of the proposed new system is positive, though we believe that it is seriously deficient in a number of aspects.

That the proposed system will oblige industry to provide safety data on the chemicals it sells, including '**no data, no market**' (at least for basic safety data).

That the proposed **system will identify the worst chemicals** (those of very high concern) and deal with them through the new authorisation system (which we see as severely flawed, see below). We welcome the scope of the definition of 'very high concern', which includes:

- chemicals that accumulate in our bodies and the environment, and are known to be toxic (PBT – persistent, bioaccumulative and toxic).
- Chemicals that accumulate in our bodies and the environment, but that are not yet known to be toxic (vPvB – very persistent, very bioaccumulative).
- Chemicals that are of equivalent concern, including endocrine disrupting chemicals.

### **However, there are a number of crucial flaws, in particular:**

#### **Continued use of the worst chemicals, even when safer alternatives are available**

The new system will identify the worst chemicals – those of very high concern – but, as currently designed, industry would be able to get permission to carry on using them, even if safer alternatives are readily available. In our view, the use of chemicals of very high concern (such as those that accumulate in breast milk) should only be allowed if industry demonstrates an overwhelming societal need, that no safer alternatives are available and that risk reduction measures will be put in place. Progressive, stepwise substitution of hazardous chemicals with safer alternatives is necessary to achieve the goal of phasing out use of the worst persistent, bioaccumulative and toxic chemicals. Consideration of availability of alternatives as an integral part of an authorisation application is also necessary to prevent the



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authorisation system from becoming bogged down with applications for unnecessary uses of chemicals of very high concern.

***Attached to this submission we provide a synopsis of information compiled by Clean Production Action for Greenpeace about the workability of substitution.***

### Secrecy remains

The current proposals would allow industry to keep a large amount of information confidential regarding the production and use of chemicals. This is against the interests of consumers, workers, downstream users and retailers.

### Untested chemicals in imported consumer products

The current proposal would allow imported products to contain untested chemicals, presenting unknown hazards to Europe's consumers.

### Unclear definitions

A number of key concepts are not sufficiently defined and/or explained. This includes adequate control, socio-economic assessment and exposure scenarios. Poor definition of such concepts leaves many aspects of the REACH system open to interpretation, particularly by the Agency and its Committees. This would not prevent political horse-trading in controlling chemicals and continue the current cumbersome and ineffective decision making.

### Inconsistency between treatment of different chemical properties of very high concern in authorisation and registration

We welcome the Commission's inclusion of substances with PBT, vPvB, CMR and ED properties in the authorisation scheme. However, in several places in the text relevant for the authorisation and registration procedure, CMRs are dealt with as a priority or specific arrangements have been provided, without considering the new scope of authorisation. E.g. the classification of preparations according to 1999/45 does not work for vPvB substances, the IPPC permitting methodology does not take the aggregated effects of releases of persistent substances into account, and the text requires early registration for CMRs but not for PBTs or vPvBs.

In addition, a number of specific comments are given below in the order required in the Commission's guidance for the internet consultation.



## 1. Duty of care

Two important improvements in the duty of care are required to ensure a workable and effective system:

Companies must be obliged to use the safest substances available. The duty of care needs to include a clause obliging industry to use safer substitutes wherever and whenever these are available.

The duty of care for those placing articles on the market (Title X) needs to be extended to ensure that the disposal of articles is properly considered. In addition the current Point 64 will allow importers to bring articles into Europe which contain unregistered chemicals, posing unknown health and environmental hazards – it is also important to create a level playing field between articles made in Europe and those imported into Europe.

Point 64 implies that substances in imported articles need only be registered if released in “sufficiently high amounts and in such a way as to adversely affect human health or the environment”. This places an unreasonable burden of responsibility upon the importer to make judgements regarding “reasonably foreseeable conditions of use”, likely quantitative releases and what constitutes a “sufficiently high amount”, a burden that may ultimately fall upon the Competent Authority. Moreover, such subjective qualifications would undoubtedly result in substantial (but undocumented) differences in the level of protection conferred. The 1t per year threshold is also open to interpretation, particularly regarding its application where one importer imports a range of different articles containing the same substance. Registration requirements must therefore apply consistently to all substances in imported articles.

*Changes/amendments needed:*

- *Point 3(1) should have the following text added at the end:*

***When selecting substances for production and use, manufacturers and downstream users shall select the safest available substance.***

- *Point 63 should be amended:*

Without prejudice to Directive 2001/95/EC of the European Parliament and of the Council, producers and importers of articles shall ensure that the articles they place on the market can be used ***and disposed of*** in such a way that human health and the environment are not adversely affected as a result of exposure to any substances released from them.

- *Point 64(1) should be changed to the following:*

A producer or importer of articles shall, ***for*** any substance contained in those articles, ~~register~~ either register that substance in accordance with Title IV or ***declare conformity with an existing registration*** ~~in quantities totalling over 1t per year, if during normal and reasonably foreseeable conditions of use and disposal the substance may be released in sufficiently~~



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~~high amounts and in such a way as to adversely affect human health or the environment.~~



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## **2. Chemical Safety Assessment**

No comments at this stage.



### **3. Information Flow**

The proposed system has crucial problems with its provisions regarding information flow and confidentiality. The lack of an obligation to provide safety information with articles even when they contain substances subject to authorisation, and the lack of any right of access to safety information for article producers and retailers will make it difficult for them to fulfil their duty of care. The system will also not allow consumer choice.

#### **Labelling of articles containing chemicals of very high concern**

We maintain the view that, as a matter of principle, chemicals of very high concern should not be used in articles. However, in cases in which use of such chemicals in articles is authorised, we consider it very important that the articles containing these Substances of Very High Concern should be clearly labelled.

*Changes/amendments needed:*

- *Insert a second paragraph in Point 63:*

***Producers and importers of articles containing substances meeting the authorisation criteria shall ensure that these articles are labelled with a clear notice to that effect and with the authorisation number/s where appropriate.”***

#### **Access to information about chemicals in articles**

Regarding access to information, the current draft proposal focuses on substances and neglects articles. There are no rules to ensure that neither producers/distributors of articles nor consumers will have access to information on hazardous chemicals in articles that they manufacture, sell or use. We propose that the information requirements of REACH are extended to cover also actors in the supply chain for products.

*Changes/amendments needed:*

- *A third paragraph should be added to Point 63:*

***Producers, importers and retailers of articles are obliged to provide their customers, on request, with the information in Point 6 regarding the substance(s) contained in those article(s). If they do not possess this information, they should obtain it from their supplier(s).***



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### **Deadline for Agency to publish information in its public database**

The current text does not give the Agency a deadline to publish information on the public database.

*Changes/amendments needed:*

- *Amend Point 67.(2)(d) to:*  
  
(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;

### **Decision making on confidentiality**

The current proposal allows a single Member State competent authority to determine the European approach to confidentiality on a piece of information, with no opportunity for challenge. This is not acceptable. It is essential that there is a procedure to allow other competent authorities or the Agency to challenge decisions on confidentiality, and then obtain an agreed position, for example using one of the Agency's Committees. Two modes of challenge should be built in, first for the other Competent Authorities and the Agency, the second for other stakeholders:

*Changes/amendments needed:*

- *Amend Point 102 (2)*  
  
Requests for confidentiality within the terms of paragraph 1 shall be considered by the competent authority of the Member State responsible for a registration or Member State authorisation, the competent authority of an evaluating Member State, or, in the case of a Community authorisation, by the Agency. The relevant authority shall decide which requests shall be granted or denied on the basis of documentary evidence produced by the registrant, downstream user, applicant or the party concerned, ***taking into account the public interest served by disclosure of environmental and health information.***
- *Delete second paragraph of Point 102(2) and insert a new point 102(3), to establishing a review body in accordance with the Aarhus Convention*



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~~Information accepted as being confidential by one of the above authorities shall be treated as being confidential by the other competent authorities, Member States, the Agency and the Commission. The Agency shall develop guidance in order to promote a harmonised approach to the application of this point.~~

*Where a person or authority is denied access to information which has been declared confidential, each Member State shall ensure that there is access to an expeditious procedure established by law that is free of charge or inexpensive for reconsideration by a public authority or review by an independent and impartial body other than a court of law.*

### **Non confidential information**

We consider that the list of non-confidential information should be extended to allow the public and business to estimate risks and make informed choices.

*Changes/amendments needed:*

- *Extend the list of information in Point 102(3) by adding:*
  - *chemical structure(s) of the substance;*
  - *full Chemical Safety Reports;*
  - *use categories;*
  - *total market volumes;*
  - *and exposure scenarios.*



## 4. Registration procedures

### **Requirements for chemicals produced in volumes below 1 t/a**

There is currently no mechanism to ensure that low tonnage chemicals of high concern are detected, nor to deal with multiple producers of low tonnage chemicals. We therefore suggest that there should be a simplified registration of those chemicals produced and imported at volumes <1 t/a, which includes information about the producer, CAS number/structure and production volume.

### **Too long deadlines – Inconsistency for CMR and other substances subject to authorisation**

We are very concerned about the long registration deadline (11 years) proposed for low tonnage substances. This would delay the establishment of a harmonised registration system for new and existing chemicals until 2017. Considering how long it will take to implement the authorisation and restriction controls this is unlikely to meet the legal obligations under the Water Framework Directive and achieve the commitments made at UN and OSPAR level. In contrast, the White Paper proposed a final registration deadline of 2012. We therefore demand a shorter phase-in deadline for low volume substances in order to have a harmonised system in place by 2014 and methods of providing an early prioritisation of problematic chemicals for further examination, for example through an early pre-registration procedure or QSAR screening.

The first deadline for registration of phase-in substances (3 years) covers only CMR-substances in Category 1 and 2 (Point 22 (1) (a) and 23 (1)). This first registration stage should also cover known PBTs, vPvBs and other substances of high concern. The link to the Authorisation system should be considered in this context.

*Changes/amendments needed:*

- *The phase in deadline in point 22(3) should be shortened by 3 years*  
Point 20 shall not apply for a period of ~~8~~ 4 years after entry into force of this Regulation to phase-in substances manufactured in the Community or imported in quantities reaching 1 tonne or more per year per manufacturer or per importer at least once following the entry into force of this Regulation.
- *Point 22 (1) (a) should cover also substances subject to Authorisation:*  
to phase-in substances classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548 **or subject to authorisation under Point 44** and manufactured in the Community or imported in quantities reaching 1 tonne or more per year per manufacturer or per importer at least once following the entry into force of this Regulation; and



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### **Sanctions: Will there be a "No data - No market" regime?**

The "No data - no market" principle appears to be implemented in the draft legislation (Point 20); however more detail is needed as to what will happen to the time frames, when registrant(s) propose(s) further testing (Annex I, point 0.5).

If a registrant fails to complete his registration, it shall be "rejected" (point 19 (3)) and the substance shall not be marketed in the Community (Point 20 (1)). However, it is unclear what that actually means in the form of possible sanctions.

*Changes/amendments needed: The practical implications of the "no data-no market" principle should be clearly specified and must not be weakened by the evaluation of testing strategies.*

### **Quality control of registration and clarification of "Intended uses"**

With the current text most registration dossiers will not be checked, which means that there will be many uncertainties as to the quality of the data.

*Changes/amendments needed: The Commission should develop a compulsory Quality Assurance scheme for registration dossiers.*

The registrant must cover 90% of substance volume in the safety report (Point 11). The remaining 10% may be marketed without use-specific risk assessment. This is of particular concern for intermediates as this provision could open the door for unspecified open uses.

In addition, the requirement for how to report "intended use" (Annex IV, section 3) should be clarified. If uses are not reported in a uniform way, the information would be of little use to consumers and other stakeholders.

*Changes/amendments needed: The Commission should clarify the "intended use" concept in order to ensure appropriate and consistent levels of reporting.*

According to Point 11, (1) (iii) the registrant shall report own and intended uses. We suggest the reporting should also make clear those uses that the registrant specifically advises against.

*Changes/amendments needed:*

Add new bullet to Point 11(1)(a):

Information about uses that the registrant advises against

### **Aggregated volumes**

Chemicals may be produced/imported in large volumes by several manufacturers or importers. For chemicals handled by a large number of importers/manufacturers there is a need for a calculation of the accumulated tonnage from all manufacturers/importers in order to evaluate whether the total volumes marketed



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should trigger more data requirements. We suggest that some total-market-volume trigger levels be built into the legislation.



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## 5. Polymers

### **Registration of polymers**

The registration of polymers is essential, due to great potential hazard of these substances and to avoid relaxation of the current application of the new substances regulation for polymers.

So far, however, the text is unclear in many points, especially regarding the scope of Point 15.

In principle the proposed concepts to deal with polymers as mixtures of oligomers or monomers and to require registration for polymers classified as dangerous, seem to be appropriate. Nevertheless the exclusion criteria of 2% oligomer/monomer content and the exclusion of polymers above 10.000 Dalton is not consistent with the Preparations Directive and the idea to use only the low molecular weight fraction for the classification and registration.

*Changes / Amendments needed: Clarification of Point 15, replacing the 2% exclusion criteria with 0.1 % in line with the Preparations Directive and deleting the 10.000 Dalton threshold.*



## 6. Intermediates

We welcome the Commission's inclusion of intermediates in registration, as we consider it is important that there is sufficient information available to evaluate the hazards of such chemicals. This registration will also give regulators a better indication of how many intermediates are in use and what their properties are. However, we consider that the minimal amount of safety information proposed is insufficient for an adequate characterisation of these chemicals, which will mean that the system will not work effectively in practice to protect human health or the environment.

We therefore propose that the information requirements for isolated intermediates on site and transported should be upgraded to those required for chemicals marketed in volumes between 1-10 t/a, annex V.

*Changes/amendments needed:*

- *Delete Point 18(2) and Point 18a(2), and replace with:*

***18(2) A registration for an isolated intermediate on site shall include the following information:***

***a) a technical dossier as specified in Point 11(1)(a)***

***b) a chemical safety report as specified in Point 11 (1)(b)***

***c) The technical dossier referred to in Point 11(1)(a) shall include under items (vi) to (viii) as a minimum the information specified in Annex V.***

***18a(2) A registration for an isolated intermediate transported shall include the following information:***

***a) a technical dossier as specified in Point 11(1)(a)***

***b) a chemical safety report as specified in Point 11 (1)(b)***

***c) The technical dossier referred to in Point 11(1)(a) shall include under items (vi) to (viii) as a minimum the information specified in Annex V.***



## 7. Data requirements

### **Does REACH provide for authorities to request additional data?**

We support the general approach with differentiated standard data requirements for different volumes of chemicals for practical reasons. However, the new system should not prevent authorities from getting any additional information, irrespective of tonnage. It is unclear if evaluating authorities need to provide justification in order to require more information from industry than that specified in Annexes V to VIII (Point 38). Authorities may require additional data from industry e.g. to do regional exposure assessments/combined exposure assessments or to get results from advanced tests etc. Authorities currently have the legal right to require such data under existing legislation and this must not be lost.

*Changes/amendments needed:*

- *Delete the words “if appropriate” in Point 38 (1) (c).*

(c) examine any information in the registration(s) as well as any other relevant information, and

require registrants or downstream users to submit further information, including, ~~if appropriate,~~ information not required in Annexes V to VIII, if the available information or the structural similarity with known substances of concern or with substances which are persistent and liable to bioaccumulate suggests that the substance or one or more of its transformation products has/have properties of concern or is persistent and liable to bioaccumulate;

- *Delete the sentence “any decision requiring further information...acquired knowledge” in point 38 (2)*

The evaluating authority shall base its evaluation of a substance on any previous evaluation under paragraph 1 or Point 35. ~~Any decision requiring further information with respect to a specific task listed above can only be justified by a change of circumstances or acquired knowledge.~~



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## **8. Data sharing/consortia formation**

We welcome the provisions on data sharing and formation of consortia..



## 9. Procedures for downstream users

Downstream users should also be obliged to report quantitatively on all uses not covered by the chemical safety report or for which alternative risk management measures are employed.

*Changes/amendments needed:*

- *Point 33 (2) should include an obligation for downstream users to report in which volumes they use the substances.*

## 10. Evaluation Procedures

The system will only be workable and effective if the registration data are accurate.

We therefore propose that increased efforts are put into checking the data submitted by industry, and that the system should return to that proposed in the White Paper, where all registrations above 100 t/a are evaluated for accuracy. We also consider that the proposal for approval of testing plans is overly bureaucratic and time consuming and should be replaced by a simplified decision procedure following a guidance document, which should be produced by the Commission.

*Changes/amendments needed:*

*Amend Point 35 as follows:*

- *delete Point 35(2)*  
~~— If the evaluating authority agrees with a testing proposal, it shall require the registrant(s) or downstream user(s) concerned to carry out the proposed test and set a deadline for the submission of the summary of the test result, or the robust study summary if required by Annex I. The evaluating authority may modify the conditions under which the test shall be carried out.~~
- *amend Point 35(1) and insert tasks a) to d) of Point 38(1) (Priority Evaluation) Including the amendment specified in section 7 (Data requirements)*

The evaluating authority shall examine any **registration dossier for a substance produced or imported at over 100 tonnes per annum with a view to performing the following tasks** ~~proposal for testing made in order to fulfil the information requirements in Annexes VII and VIII contained in registrations or downstream user reports for a substance, irrespective of the tonnage level at which they are proposed:~~

*(a) examine the information in the technical dossier(s) submitted in order to fulfil the information requirements in Annexes V and VI, and*



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*require the registrant(s) to submit any information that is needed to bring the technical dossier(s) into compliance with those information requirements;*

*(b) examine:*

- whether the registrant’s own use(s) and the intended use(s) represent at least 90% of the volume manufactured or imported, and*
- the adaptation statements and their justifications in the technical dossier(s) submitted in order to comply with the information requirements in Annexes V to IX, and*

*require the registrant(s) to submit any information that is needed to bring the technical dossier(s) into compliance with those information requirements;*

*(c) examine any information in the registration(s) as well as any other relevant information, and*

*require registrants or downstream users to submit further information, including information not required in Annexes V to VIII, if the available information or the structural similarity with known substances of concern or with substances which are persistent and liable to bio-accumulate suggests that the substance or one or more of its transformation products has/have properties of concern or is persistent and liable to bio-accumulate;*

*(d) examine information submitted by several registrants and aggregate the tonnages, and*

*on the basis of aggregated tonnage require the registrant(s) to submit information in order to fulfil the information requirements in Annexes VII and/or VIII, unless such information has already been provided by one of them.*



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## 11. Authorisation

### Scope of authorisation

We support the Commission in their inclusion in authorisation of chemicals with the following criteria:

- carcinogens, mutagens and reproductive toxins.
- persistent, bioaccumulative and toxic chemicals, very persistent, very bioaccumulative chemicals and chemicals of equivalent concern, including endocrine disrupters.

However, we believe that substances, which are known to be potent respiratory sensitisers and priority hazardous substances as identified through the Water Framework Directive or the OSPAR Convention should be added.

*Changes/amendments needed:*

- *Chemicals meeting the following criteria should be added to Point 44:*
  - 44(g) substances which are known to be potent respiratory sensitisers in accordance with Point 47*
  - 44(h) priority hazardous substances as identified through the Water Framework Directive 2000/60/EC*
  - 44(i) substances of concern identified by the OSPAR Commission in accordance to Point 47.*

### Granting of an authorisation

In our view, in order for REACH to achieve the objectives laid out in the White Paper it is essential that substitution, the replacement of more hazardous chemicals or processes by those that are less hazardous, should be the core goal of the authorisation process. The use of chemicals subject to authorisation should only continue where there are no safer alternatives and there is an overwhelming societal need and risk reduction measures are in place.

We strongly object to the way in which the current text will allow industry to continue using chemicals of very high concern, even when safer alternatives are available. In our view, allowing industry to continue using chemicals if they claim ‘adequate control of risk’ (Point 48 (2)) will fail to deal with the threat posed by these chemicals, as many have no threshold of action, have low dose effects or will cause long term contamination. The current text will also make the authorisation system unworkable due to a very large number of requests for authorisation being received from companies who wish to continue using chemicals of very high concern, as companies will not need to consider whether safer alternatives are available prior to application.



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All applications for authorisation should go through an improved Point 48 (3).

Although the route to authorisation defined in 48(3) does allow a consideration of need and alternatives, it does so only after detailed consideration of risk for the substance of very high concern. This will lead, in some cases, to an unnecessarily burdensome procedure prone to the same delays and inaction as the current system. The first step of an authorisation procedure should be consideration of alternatives and an assessment of alternatives should be included in the application. In some cases this will obviate the need for a detailed evaluation of risk and could also prevent applications for authorisation where safer alternatives clearly exist.

The phrase "however, the existence of an alternative is in itself insufficient grounds to refuse an authorisation" (Point 48 (3c)) is particularly unacceptable, as it clearly implies protection of the health and environment is a secondary consideration. The presumption should be that where a substitute is available, an authorisation will not be granted.

Changes/amendments needed:

- *Point 48 (2) should be deleted, removing the 'adequate control' route to authorisation.*
- ~~— An authorisation shall be granted if the risk to human health and/or the environment from the use of a substance arising from the intrinsic properties specified in Annex XIII is adequately controlled.~~
- ~~— The granting authority shall not consider:~~
- ~~— (a) the risks to human health and the environment of emissions of the substance from an installation to an environmental compartment if the applicant demonstrates that the substance is regulated by a binding emission limit value for that compartment in a permit granted in accordance with Directive 96/61/EC, or~~
- ~~— (b) the risks to human health and the environment of emissions of the substance from a site to the aquatic compartment if the applicant demonstrates that the substance is regulated by a binding emission limit value or environmental quality standard in a permit granted in accordance with Directive 2000/60/EC;~~
- ~~— (c) the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC.~~
- *Point 48(3) should be amended as follows:*



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~~If an authorisation cannot be granted under paragraph 2, a~~An authorisation may be granted ***only if there is an overriding societal need for this use of the substance, and this need outweighs any risk to human health and the environment*** ~~socio-economic benefits outweigh the risk to human health and/or the environment arising from the use of the substance.~~ This decision shall be taken after consideration of the following elements:

(a) ~~the risk posed by the uses of the substance;~~

(b) ***the societal need for the substance. An authorisation shall be rejected if there is no overriding societal need for this use of the substance*** ~~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) all available information on alternative substances or technologies. ***If such a substitute is available, and this substitute does not itself fulfil the criteria laid out for chemicals of very high concern in Point 44, and itself carries no other identified hazards that give equal cause for concern for the intended use, then the application for authorisation shall be rejected*** ~~Substitution shall be considered; however, the existence of alternatives is in itself insufficient grounds to refuse an authorisation.~~

(d) ***In cases in which there is an overriding societal need and no safer alternatives are currently available, an authorisation should only be granted if the risk management measures put in place are sufficient to minimise the risk posed by the substance, taking into account any other known uses and release of the substance. The applicant should also supply, within one year, a substitution plan.***

- *Point 50 (5) should be amended consequently to:*

The application ***shall*** ~~may~~ include:

- (a) a socio-economic analysis conducted in accordance with Annex XV;
- (b) available information on the health and/or environmental risks of any alternative substances or technologies.

In addition, it is important that authorisation applications do consider the risks in full to human health and the environment, even where emission limits exist. For example, Integrated Pollution Prevention and Control (IPPC) is not a suitable instrument to deal with persistence and bioaccumulation where many small but widely dispersed emissions can be reconcentrated via the food chain. Regulation by emission limit values are not a suitable means for dealing with chemicals of very high concern and



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cannot ensure a high degree of protection for human health and the environment, particularly PBT and vPvB substances. Therefore

- *Point 50 (6) a) and b) should be deleted.*

The application shall not include:

- ~~— (a) the risks to human health and the environment of emissions of the substance from an installation to an environmental compartment if the substance is regulated by a binding emission limit value for that compartment in a permit granted in accordance with Directive 96/61/EC. The applicant shall make a specific reference to that permit;~~
- ~~— (b) the risks to human health and the environment of emissions of the substance from a site to the aquatic compartment if the substance is regulated by a binding emission limit value or environmental quality standard in a permit granted in accordance with Directive 2000/60/EC. The applicant shall make a specific reference to that permit;~~
- (c) the risks to human health arising from the use of a substance in a medical device regulated by Council Directive 90/385/EEC, Council Directive 93/42/EEC or Directive 98/79/EC.

### **Agency opinion and alternatives**

*Changes/amendments needed:*

- *Extend the Agency's task under to 52(5):*

The Agency's opinion shall include the following elements:

- (a) an assessment of the risk to health and/or the environment arising from the use(s) of the substance as described in the application;
- (b) an assessment of the socio-economic factors associated with the use(s) of the substance as described in the application, when an application is made in accordance with Point 50 (5).
- c) an assessment of the information obtained on alternative substances and technologies.*

### **Socio-economic Analysis (SEA)**

The SEA will play a major role in the decision making. The current text in annex XV leaves the scope and level of detail in the SEAs very open and may lead to cumbersome discussions and political bargaining. This, we believe, is one of the major weaknesses of the authorisation procedure. It is not appropriate to give



individual actors or the technical committee such a political role to define what an SEA is. The democratic legitimacy of the decision making is at stake. We therefore suggest that Annex XV should focus on the assessment of the benefits to the public and the environment of not being exposed to hazardous substances.

### **Reviewing authorisations**

All authorisations should be temporary. A regular review should take place to ensure that safer alternatives are brought into use as rapidly as possible, and to ensure an effective response is made to any new information on the safety of the substance.

*Changes/amendments needed:*

- *Point 48(6) should be amended to*  
Authorisations ~~shall~~ *may be temporary and* subject to ~~conditions, including~~ *a review period of not more than 5 years. Authorisations may also be subject to other conditions.*
- *Point 49(2) first paragraph should have the following sentence added at the end:*  
*Authorisations shall be reviewed if new information emerges which could affect the decision to authorise a use, including new information on availability of safer alternatives.*

### **Authorisations in the supply chain**

The Regulation must ensure that substances of very high concern are properly controlled throughout the supply chain. The current text controls the use of chemicals by a company making an article from raw materials, but the controls do not properly stretch downstream to further companies that may use this article to make other articles (e.g. a company making a chair from dyed fabric, a filling and wood). They also do not protect EU consumers against hazards resulting from the import of articles from outside the EU which contain chemicals of very high concern. This could provide an incentive for manufacturers of articles to shift production out of the EU.

*Changes/amendments needed:*

- *Point 54 should read as follows:*  
Holders of an authorisation shall include the authorisation number on the label before they place the substance *or preparation* on the market for an authorised use. *This authorisation number should be communicated down the supply chain to all downstream users including producers of articles.*
- *Point 45(1) - should have the following text added at the end:*  
Manufacturers, importers and downstream users shall not use substances included in Annex XIII unless, in accordance with this Regulation, the



use(s) of the substance on its own, in a preparation or the incorporation of the substance into an article have been exempted from the authorisation requirement in Annex XIII, or authorised by a decision, and the substance is being used within the conditions of the exemption or authorisation. ***An importer or producer of articles shall be subject to the same requirements with respect to the substances included in the articles they import or produce.***

### **Exclusions**

We are concerned that the exclusions from authorisation will jeopardise both the level of protection for human health and the environment and the role of REACH as the overarching framework for the control of substances. Therefore we would suggest the following alterations:

*Changes/amendments needed:*

- *Add at the end of 45(3):*  
Paragraph 1 shall not apply to the following uses of substances ***as long as the legislation cited provides an equivalent or greater level of protection for human health and the environment as this authorisation procedure:***
  
- *For Points 45(3a-c) add*
  - (a) uses ***as an active ingredient*** in plant protection products within the scope of Council Directive 91/414/EEC<sup>1</sup>;
  
  - (b) uses ***as an active ingredient*** in biocides within the scope of Directive 98/8/EC<sup>2</sup> of the European Parliament and of the Council;
  
  - (c) uses as ***an active ingredient*** medicinal products for human or veterinary use within the scope of Council Regulation 2309/93<sup>3</sup> and Directives 2001/82<sup>4</sup> and 2001/83<sup>5</sup> of the European Parliament and of the Council;

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1 OJ L 230 , 19.08.1991, p.1

2 OJ L 123 , 24.04.1998, p. 1

3 OJ L 214 , 24.08.1993, p. 1

4 OJ L 311 , 28.11.2001, p. 1

5 OJ L 311 , 28.11.2001, p. 67



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- *Delete 45 (3g).* (Any exemptions for isolated intermediates on site or transported should be through 46(2)).  
~~— uses as an isolated intermediate on site or as an isolated intermediate transported.~~

- *Delete 45(4).* (CMR Substances used in food contact materials should be subject to authorisation).

For substances that are subject to authorisation only because they meet the criteria in Point 44 (a) to (c), paragraph 1 shall not apply to the following uses of these substances:

(a) uses in cosmetic products within the scope of Council Directive 76/768/EEC<sup>6</sup>;

- ~~— (b) uses in food contact materials within the scope of Council Directive 89/109/EEC.~~

- *Delete 45(5).* (This paragraph could allow preparations with less than 25% of a vPvB/PBT to escape authorisation).

- ~~— Paragraph 1 shall not apply to the use of substances in preparations below the concentration limits specified in Directive 1999/45/EC which result in the classification of the preparation as dangerous.~~

### **Giving up authorisations**

The text currently does not include a mechanism for a company to give up an authorisation, for example if they decide to use a safer alternative. Such a mechanism will also need to deal with subsequent applications that have used this authorisation through a letter of access (Point 51).

### **Exemptions**

It is important that any exemptions do not reduce the protection of human health and the environment. Emission limit values for persistent bioaccumulative substances do not offer this protection:

*Changes/amendments needed:*

- *Point 46(2), delete “emission limits” in (a) and extend final sentence:*

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<sup>6</sup> OJ L 262 , 27.09.1976, p. 169



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Uses or categories of uses may be exempted from the authorisation requirement. In the establishment of such exemptions, account shall be taken of:

(a) existing specific Community legislation imposing minimum requirements relating to the protection of health and/or the environment for the use of the substance (eg. binding occupational exposure limits, ~~emission limits, etc~~);

(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 should only be permitted if an equivalent or greater level of protection as that provided by the authorisation procedure will be achieved.*** Exemptions may be subject to conditions.

### **Annex XII – Criteria for identification of PBT or vPvB**

We consider that these criteria are overly prescriptive, and do not reflect the state of the science as laid out in the Technical Guidance Document on Risk Assessment (European Commission, 2003). For example, Annex XII, 1.2 states:

“The assessment of bioaccumulation **shall be based** on measured data on bioconcentration in aquatic species.” [Our emphasis]

Whilst the Technical Guidance Document (Part II) states in section 4.4.4.3:

“When measured BCF values are not available the  $K_{ow}$  or the BCF based on modelling can be used to indicate the liability to bioaccumulate from water. For substances with  $\log K_{ow} < 6$  assessment on the basis of  $K_{ow}$  or estimated BCF does not make a real difference since all available BCF models are linear (see Section 3.8.3.2). The B criterion for  $\log K_{ow}$  is therefore directly derived from this linear relationship. A substance is considered to potentially fulfil the B criterion when  $\log K_{ow}$  exceeds a value of 4.5.”

*Changes/amendments needed: The criteria in Annex XII should be brought into line with those in the Technical Guidance Document.*

### **Concern over timeframe**

The timeframe for implementation of authorisation is unclear. When will the first substance be included in Annex XIII (point 46)? How many substances can be handled each year? And when will the authorisations be in place for all those substances, that should be regulated through authorisation? The key issue in this matter seems to be the speed with which substances are included into Annex XIII (the list of substances subject to authorisation) and the period between inclusion into



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Annex XIII and the “sunset date”. Efforts should be made to handle a large number of substances each year - clear targets should be set - and the necessary resources to do this work should be allocated.

*Changes/amendments needed:*

- *Amend Point 46 (5) to:*

The number of substances included in Annex XIII and the dates specified under paragraph 1 shall take account of ***international commitments, including the UN WSSD and OSPAR Convention generation targets available resources.***



## 12. Restriction Procedures

The restriction process seems to be very slow. It appears that 14 months will pass from when the legislation enters into force until the first restrictions are in place (Title IX). Efforts should be made to speed up this process.

Restrictions do not apply to substances in waste if handled under permission of authorities. This applies, even if recycling takes place and hence the substance may re-enter marketed products. There is a need to reconsider the formulation since it may create a loophole in the life cycle approach of REACH.

*Changes/amendments needed:*

- *Speed up the process of amending Annex XVI as described in Title IX.*
- *57 (1): Delete the last sentence:*

When there is an unacceptable risk to human health or the environment arising from the manufacture, use and/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 Point 113 (3) by adopting new restrictions, or amending current restrictions in Annex XVI, for the manufacture, use and/or placing on the market of substances on their own, in preparations or in articles, pursuant to the process set out in Points 58 to 62. ~~This shall not apply to the use of a substance as an isolated intermediate on site.~~



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### **13. The Agency**

No comments at this stage



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## **14. Other**

### **Legal basis**

The regulation should be governed by article 175(1) to allow Member States to have a higher level of protection if they wish. This is particularly important to ensure that no Member State experiences a reduction in protection, and in view of the uncertainty as to the eventual shape of this legislation.

### **Classification and labelling**

We support the establishment of a classification and labelling inventory administered by the Agency. The harmonised classification and labelling system should be extended to cover all those properties, which are included in the authorisation system – not only the CMR's and respiratory allergens, but also PBTs, vPvBs and EDC's. The long-term perspective should be the establishment of a harmonised classification and labelling system for all hazardous substances.

We also suggest that the classification and labelling inventory should contain available data from chemicals, which were tested but not classified for certain endpoints and the reasons for not classifying. The reasons for non-classification should be publicly available. Moreover the inventory could also cover available data for substances produced in amounts below 1 t/a (see section 4).

### **Use of non-animal tests and preventing duplicate animal tests**

There is significant potential to increase development of effective non-animal tests. Both the European Commission, Member States and the chemical industry have a responsibility to commit resources to the development and validation of such tests. Consideration should be given to examining how this regulation could accelerate this process, for example through the Agency encouraging the development and use of non-animal tests, through measures to ensure industry invests appropriate resources in developing non-animal tests and through an increased effort to validate and harmonise non-animal testing methods.

Further, REACH must ensure that duplicate animal testing does not take place. Therefore industry should be required to publicise and make available all existing animal test data in their possession or control. Penalties must be in place for companies failing to meet this requirement. Test plans must be submitted for a 120 day public comment period in which existing data can be brought forward by other stakeholders or submitted by industry, and after which, test plans can be modified.

As REACH goes forward, decision makers need to ensure that focused chemical testing will rely on non-animal methods wherever these are available. Even where non-animal test methods are not available, the regulations should prohibit any outdated or unnecessary animal testing. At the same time, it is critical that increased funding be made available to develop non-animal tests as a matter of urgency. REACH should be designed and implemented so as to enable the swiftest possible



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transition away from animal testing, consistent with placing the fewest animals at risk of exposure to harmful chemicals, whether in the wild or in laboratories.



**Annex: The Workability of Substitution : Safer Chemical Use Within Reach**

**The following information has largely been compiled by Clean Production Action for Greenpeace. This compilation represents an initial step of an ongoing research project on applications of substitution principle in legislation and in practice.**

**1. There is precedence of substitution in existing European legislation:**

- “The employer shall implement the measures referred to...[to encourage improvements in the safety and health of workers at work] ... on the basis of the following general principles of: replacing dangerous by the non dangerous or the less dangerous”. (Council Directive 89/391/EEC on introduction of measures to encourage improvements in the safety and health of workers at work, article 6.)
- “The employer shall reduce the use of a carcinogen at the place of work, in particular by replacing it, in so far as is technically possible...” (Council Directive 90/394/EEC on the Protection of Workers from the Risks related to Exposure to Carcinogens at Work, article 4.)
- “The Commission shall take into account...the availability of substitutes,” with particular reference to the progressive substitution of cadmium. (Directive 2000/53/EC of the European Parliament and of the Council on End of Life Vehicles.)
- “...the most effective way of ensuring the significant reduction of risks to health and the environment relating to those substances which can achieve the chosen level of protection in the Community is the substitution of those substances in electrical and electronic equipment by safe or safer materials. Restricting the use of these hazardous substances is likely to enhance the possibilities and economic profitability of recycling of WEEE and decrease the negative health impact on workers in recycling plants....As soon as scientific evidence is available and in accordance with the principles on chemicals policy as laid down in the Sixth Community Environment action Programme, on the prohibition of other hazardous substances and their substitution thereof by more environmentally friendly alternatives which ensure at least the same level of protection of consumers should be examined.” (Directive 2002/95/EC of the European Parliament and of the Council on the Restriction of certain Hazardous Substances in Electrical and Electronic Equipment)
- The focus on cadmium and safer substitutes is underscored in the Directive on the restriction of certain hazardous substances, which accompanies Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE). Reference is made to a Council Resolution of 1988, which stresses that the use of cadmium



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should be limited to cases where suitable and safer alternatives do not exist.

## **2. There is a clear mandate to implement substitution under the new EU chemicals legislation**

The recent Ministerial Meeting of the OSPAR Commission, held in Bremen in June 2003 and attended by representatives of many EU Member States, agreed upon a statement including *inter alia* specific reference (paragraph 23c) to the need for substitution to form an integral part of the new EU legislation:-

“23. In this context, we note that further efforts are required to meet the objectives of the OSPAR Hazardous Substances Strategy and its 2020 cessation target. We acknowledge that different, but complementary, one-generation targets have been included in the Plan of Implementation of the World Summit on Sustainable Development and in the EC Water Framework Directive. In the further development of the EC Chemicals policy we encourage the European Community:

- a. to take full account of the need to protect the marine environment;
- b. to take account of our commitments to move towards the cessation of emission, discharges and losses of hazardous substances;
- c. to promote the substitution of hazardous substances with safer alternatives, including promoting and facilitating the development of such alternatives where they do not currently exist;
- d. to ensure that purchasers and consumers are provided with information on hazardous substances in goods, to help reduce the risks from them.”

OSPAR Ministerial Statement [[http://www.ospar.org/eng/html/md/Bremen\\_statement\\_2003.htm](http://www.ospar.org/eng/html/md/Bremen_statement_2003.htm)]

It should be noted that, whereas progress towards substitution can be (and indeed has been) made through the initiatives and actions of progressive companies and/or consortia, the attitude of regulatory authorities has a vital role to play in driving substitution forward on a more universal and consistent basis.

## **3. Regulation Drives Substitution**

**The information presented below was compiled from a range of sources by Clean Production Action, including telephone interviews with representatives from individual companies, and should be taken as an indication of current trends and existing achievements in practical substitution rather than as a definitive guide. This information is correct to the best of our knowledge at the time of submission. However, it is important to bear in mind that company policies and practice are subject to change at any time.**

- Lead has been widely used in the electronic industry for use in solders. Lead-free solders have existed for many years but it was the mandate in the RoHS Directive to have products free of lead by July 2006 that spurred industry research, planning



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and adoption of the substitutes. (SEEBA/Centre for Sustainable Design, UK, 2003)

- The benefits of mandatory pollution prevention planning have been demonstrated in the state of Massachusetts, USA, where over 550 companies had to assess toxic use reduction options with technical help supplied by universities and government experts. Toxic use reduction strategies included material substitution and product reformulation. Within ten years industry has reduced the use of toxic chemicals by 40%, byproduct waste by 58% and toxic emissions by 80%. A cost benefit analysis reveals that the same companies saved a total of 14 million dollars over this period through the adoption of more efficient and safer processes. The programme is ongoing and has been expanded to community outreach and assessment of substitutes for some hazardous material flows and products within the state. (TURI 2003, Toxic Use Reduction Institute website lists the legislation, outline of the plan procedure and results; [www.turi.org](http://www.turi.org))
- While manufacturers in Europe were responding to the impending WEEE and ROHS directives, Japanese companies strategically positioned themselves as promoters of greener products, and took the lead in finding substitutes for lead solder in electronics. As a result Japan developed lead-free soldering technologies well ahead of the WEEE directive timescale and ahead of European and American counterparts. (NPL, 2002 National Physical Labs. Richards, Brian. Lead-free Soldering <http://www.npl.co.uk/ei/news/epparticle.html>)

Some progressive companies have gathered hazardous substances lists and agreed on substances that need to be avoided. Many are instructing their suppliers to phase out a range of carcinogenic, mutagenic and reproductive toxins as well as some persistent bioaccumulative substances and endocrine disrupting chemicals. However, while the proactive efforts of some industry leaders telling their suppliers to avoid certain listed chemicals demonstrates that substitution is already a feasible goal, this will not, in itself solve the global crisis of increasing chemical contamination. Such action needs to be universal and across all industry sectors and size of firms. Industry needs clear criteria in which to operate and innovate. In particular small and medium size enterprises need clear criteria to chart their way forward in a competitive economy.

A common complaint from downstream users of chemicals is that information is missing to characterize adequately the risk of chemicals. Increased chemical information under REACH will change this situation as long as data are transparent, readily available and accessible to the public. But collecting information on chemicals in the absence of a clear goal to research and implement a safer processes or product redesign could lead to the entrenchment of hazardous chemical use within a more costly end of pipe management control.



## **4. Case Studies Show That Companies Can Put Substitution Into Practice**

### **4.1 Substituting Brominated Flame Retardants**

BFRs are used in a wide range of consumer products: electronic components, textiles, foam in upholstery and carpets, and building materials – all uses where the risk of fire necessitates caution. The increase in the use of more plastics and flammable synthetic materials has contributed to the increase in the use of flame retardants.

As evidence grew by the late 1980's of the dangers of brominated flame retardants, particularly PBB and PBDEs, Germany, Denmark, the Netherlands and Sweden began restricting and banning their use. In a declaration of intent in 1989, the chemicals industry and plastic manufacturers in Germany declared that they would neither produce nor use PBDEs.

The electronics industry moved quickly to find alternatives ranging from material substitution (replacement of halogenated flame retardants with non-halogens) to function substitution (replacement of plastic with metal housings). Much of the stimulus for better design and less hazardous materials has come from the WEEE and RoHS Directives and its emphasis on recycling and chemical bans. (Envirowise, 2001)

As concern around bromine compounds grew, industry moved away from those under the greatest legislative pressure (PBDEs and PBBs). However as the market for PBDEs and PBBs has declined, sales of brominated compounds such as TBBP-A and HBCD have grown in equal measure. Meanwhile, understanding of the toxicity and persistence of TBBP-A and HBCD has increased and pressure to address brominated flame retardants as a class is mounting. Concomitantly the development and supply of non- halogenated chemicals has increased.

As information grew on the risks and feasibility of some of the phosphorous-based alternatives, some companies developed non-phosphate alternatives. Product design is increasingly looking at non chemical alternatives to flame prevention, such as the use of metal casings instead of plastics.

REACH will obviously help fill this much needed gap in information. Some alternative compounds are in need of more research depending on the type of mix used. Specific information on the exact chemical composition was generally not available. However, it is vital to remember that, within the context of Substitution Assessment planning, substitution is not a simple process. It also takes account implicitly of the need to develop effective alternatives where they are not already available and to adapt rapidly to technical progress.



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An analysis of possible substitution choices for BFRs in the computer and auto industry was conducted in Germany and subsequent stakeholder sessions were held to further discuss the types and feasibility of alternatives. (UBA, 2001. Substituting Environmentally Relevant Flame Retardants: Assessment Fundamentals. ISSN 0722-186X, March 2001. Cited in Growing Threats: Toxic Flame Retardants & Children's Health. Environment California Research and Policy Center. 2003, also <http://www.umweltbundesamt.de>). Substitution included:-

*using non-flammable materials:* merely substituting flammable with non-flammable materials, e.g. plastic with ceramic circuit boards, can render the use of flame retardants unnecessary; and

*preventing fire risk by improving design:* Increasing the distances between possible flashpoints and flammable materials may be sufficient.

**Apple** has shifted from plastics to metal alloys, driven in part by the flame retardant restrictions of WEEE and RoHS. Internal metal "shields" protect computer housings from internal sparks, and can therefore allow use of non-flame retardant plastics. The next generation of Apple products will move away from polycarbonate housing and towards metal housing, using an aluminium alloy. Life cycle assessments show that although mining of metals increases energy use, the use of metals provides for better end-of-life management (than plastics), provides a better heat sink (than plastics) and enables the product life to be extended. The use of aluminium alloy shows little weight change, compared with polycarbonates. In addition, the use of lacquers in metal finishes does not cause problems during smelting, but the use of lacquers on plastics renders the plastic non-recyclable. The next generation of Apple laptop, will also have a detachable keyboard to enable access to RAM and motherboard for upgrading and disassembly at end of life.

**Sony:** In response to the German dioxin ordinance of 1994, Sony Europe started investigating safer substitutes for halogen-based flame retardants. Sony has developed halogen free circuit boards used in European television sets, VCRs and DVD players. Printed wiring boards use resin, which is an inherently flammable material. Sony's engineers adopted a resin structure containing nitrogen to increase heat resistance and modified the content and dispersibility of the phosphate compounds and fillers. Since the circuit boards must be completely halogen free, Sony also substituted phthalocyanine green, which contains chlorine with phthalocyanine blue as the photoresist pigment that covers the board's surface. By substituting all chlorine, and bromine based chemicals with safer alternatives, there is no longer a risk of dioxin formation throughout the products life cycle.

Until recently halogen-free products were only available in Europe but Sony now has adopted global design standards to ensure that all their projects meet the same standards. Sony aims to have all product lines free of BFRs by the end of 2005 if substitutes are found to be safer. They also aim to phase out all uses of vinyl chloride by 2005 as well as lead solder, and the heavy metals listed in the RoHS Directives.



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Details of their phase out of hazardous materials are given for specific product lines in their year-end report. For example a Walkman model has PVC free cables, no BFRs or lead solder in the printed wiring board. (Sony, 2003 Presentation at SEEBBA Conference May, 2003 UK. Also Sony 2002 Report at <http://www.sony.net/SonyInfo/Environment>)

### 4.2 Substituting Lead

The WEEE Directive was a major catalyst for research and adoption of lead free solutions in electronic equipment. The range of alternatives to lead in soldering range from tin (Sn), silver (Ag), copper (Cu), bismuth (Bi) and zinc (Zn). These heavy metals do not present the same level of hazard as lead. (EEB, 2001)

**NEC selected** the use of Sn-Ag-Cu in their pagers by December 1998; the use of Sn-Zn-Bi in their notebooks PCs by October 1999; the use of Sn-Ag0Cu in their main computers and equipment by 2002. **Fujitsu** selected the use of Sn-Ag-Cu for their high-end servers by October 1999; the use of Sn-Bi-Ag for their main board; and all new products to use Sn-Ag-Cu, Sn-Bi-Ag by the end of 2002. **Sony** selected the use of Sn-Ag-Bi-Cu for use in their digital video cameras by March 2000; and all products, electronic components and maintenance services to be lead free by end of March 2006. **Hitachi** selected the use of Sn-2Ag-2Bi-0.5Cu in video cameras, vacuum cleaners, and washing machines by spring 1999; and all new products will use Sn-Ag-Cu, Sn0Bi+Ag-Cu (+Bi/In) by March 2002. **Matsushita** selected the use of Sn-Ag0Bi in mini disks by September 1998; and all new products to use Sn-Ag-Cu, Sn-Ag-Bi by March 2003. **Panasonic** achieved the full adoption of Pb-free solder using Sn-Cu in 2001. **Philips** has developed new lighting for cars – the Philips HiPerVision Technology, which provides lighting for the automotive industry and uses 99% less lead. (Philips website as of June 2003. Chemicals list for products and processes <http://www.semiconductors.philips.com/profile/env/information/substances/index.html#subs>. Also: <http://www.philips.com/Assets/Downloadablefile/sustainability-2153.pdf>)

### 4.3 Substituting Organotin Compounds

Organotin compounds are used as stabilizers in plastics, especially PVC, and tributyltin is used as a treatment against dust mites and mould in some carpets and PVC floorings.

**Marks and Spencer** targeted the substitution of alkyltins in the dyeing and finishing of clothing, along with azo dyes and APEs some years ago. Their product specialists are working with the Green Chemistry department at York University to explore safer alternatives.



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#### 4.4 Substituting Alkylphenols

Alkylphenols and their derivatives are primarily used as non-ionic surfactants in industrial detergents, though also used in textile and leather finishing treatments, water based paints and as components of some personal care products.

**Boots** decided to phase out alkylphenols in 1999 and by 2000 they had achieved 90% phase out. A difficulty was first identifying where APEs were used in their 40,000 to 50,000 product range as some of their supply chains were complex. In general they have substituted alcohol ethoxylates as replacements for APEs. (Thorpe, Beverly. Clean Production Action, 2003 - based on comments made by Boots to the author during a telephone interview). Unlike APEs, alcohol ethoxylates appear to be readily and completely broken down in the environment.

Other than a phase out of all BFRs, **H&M** have achieved a strict phase out of APEs, organotins, azo dyes and all carcinogenic dyes, PVC, Bisphenol-A, phthalates, Antimony and a wide range of heavy metals as well as chlorinated aromatic hydrocarbons. They stipulated a clear set of criteria to all their suppliers, used testing to ensure compliance and relied on their suppliers and chemical formulators to provide alternatives. (Thorpe, Beverly Clean Production Action, 2003)

#### 5. The Need to Keep Substitution in REACH

Safer substitution is clearly feasible. Case studies demonstrate that industry leaders are moving to clean up their supply chain and chemical suppliers have the ability to develop Green Chemistry initiatives. What is needed now is for REACH to make substitution an operational standard for all companies.

