



navigating REACH

AN ACTIVISTS' GUIDE TO USING AND IMPROVING
THE NEW EU CHEMICALS LEGISLATION





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NAVIGATING REACH: FOREWORD

In 1998, at an informal meeting of the Environment Ministers of EU Member States in Chester, UK, Ministers expressed their concern about the lack of action on hazardous substances and highlighted the need for a new policy on chemicals. This was the beginning of what became known as REACH¹ – a new regulation on chemicals which would shift from permissive and patchy legislation to a more comprehensive system based on sound information and the precautionary principle. The regulation was intended to improve the protection of human health and the environment from the adverse effects of hazardous chemicals².

FOREWORD

The Ministers were responding to increasing awareness about the effects of chemicals on health and the environment, which continues to be a growing problem. In Europe and around the world, synthetic chemicals are present in everyday consumer items from personal care and cleaning products to clothes, toys, furniture and kitchen utensils; we are directly exposed to them in our everyday lives. Many of these chemicals are released into the environment and globally dispersed. They accumulate in wildlife such as seals and polar bears – and in our bodies. Research into the presence of industrial chemicals in the human body, from new-born babies to adults, has shown that we are continuously exposed to a multitude of chemical pollutants. Yet the vast majority of them have never been properly assessed for their human and environmental safety. A growing number of chemicals are associated with health problems such as allergies, lower fertility, damage to DNA and cancer.

REACH set out to address this huge problem. Debates surrounding its shaping have attracted world-wide attention, and provoked what has been described as the fiercest lobbying battle in EU history. During the consultation phase, from May to October 2003, the European Commission received more than 6,000 contributions from industry associations, governments, non-governmental organisations (NGOs) and the public, before it finally presented the REACH proposal.



Poster image created by Greenpeace to expose the Commissioners' role in undermining a strong REACH. © Greenpeace.

In order to ensure a strong REACH a number of European NGOs joined forces and worked intensively together to influence the development of REACH and ensure that it would effectively deliver its protection goals for human health and the environment. This coalition represented a broad range of health and environmental groups, women's groups and consumer organisations such as:

- European Environmental Bureau (EEB)
- Friends of the Earth Europe (FoEE)
- Greenpeace
- Health and Environment Alliance (HEAL), formerly known as EPHA Environment Network or EEN
- Women in Europe for a Common Future (WECF)
- WWF European Policy Office
- BEUC, the European Consumers' Organisation
- Eurocoop, the European community of consumer cooperatives.

1 | Stands for Registration, Evaluation, Authorisation and restriction of Chemicals Regulation (EC) No 1907/2006 (and Directive 2006/121/EC).

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en08500856.pdf

2 | See detailed information on scope of REACH p. 9-11.

Amongst these, Friends of the Earth Europe, Greenpeace and the European Environmental Bureau set up the Chemical Reaction project as an outreach project³ to engage other NGOs and the public in the REACH negotiations.

The cohesive and closely co-operating NGO coalition argued for key improvements to the legislation and limited some of the impact of the chemical industry's attempts to weaken REACH. It was also crucial to the effectiveness of the work that the NGOs agreed upfront to prioritise the substitution of hazardous chemicals by safer alternatives.

Despite the odds, the final version of REACH succeeds in taking the first steps towards a new approach to chemicals management. It puts the burden of proof onto the producers to show that their chemicals are safe, allows the public to get information about the use of some substances of concern in products and provides for some of the most hazardous chemicals to be substituted when there are safer alternatives.

But REACH also contains serious loopholes and legal uncertainties. As a result the law remains vulnerable to further pressure by the chemical industry, which – mindful of their profits - can be expected to try to keep some of the most hazardous chemicals on the market, even in those cases where safer alternatives are available.

Careful monitoring of REACH as it is put into practice, especially during its early stages, is imperative. The health, environmental, women's and consumer advocates involved in the legislative process believe that public participation and continued co-operation among NGOs will be essential to scrutinise the new European Chemicals Agency in Helsinki and to make sure that REACH becomes an effective tool to protect the environment and public health. The engagement of campaigning groups and the public at national level will be equally crucial to secure future substantial improvements in REACH, using the opportunities of the forthcoming reviews.

This handbook aims to explain how REACH will work, what main issues are at stake and how the law will be implemented, i.e. put into practice by the authorities. The guide also highlights opportunities to make the most of REACH by using the new provisions that were fought for – and the opportunities to improve the legislation. It points to provisions and mechanisms that NGOs and citizens can use to promote safer chemicals and lead ultimately to better protection of human health and the environment from the adverse impact of hazardous chemicals.

Last but not least, it invites non-EU NGOs to make the best use of REACH by working with the publicly available hazard information to inspire their chemical-related campaigns. This handbook also points out the current loopholes and flaws that need to be avoided as activists work to spark strong policy reforms in other regions of the world. Especially if you have not been involved in the REACH legislative process, this handbook will help you get involved and make a difference, striving towards a toxics free future.



17th May 2004 - BRUSSELS, BELG IJM. Greenpeace activists reconstruct a medieval court case with a Greenpeace 'Jacques Chirac' and a toxic Mickey Mouse 'Chemickey' - awaiting his fate on the gallows, while straddling one barrel containing consumer products known to contain harmful chemicals and the other barrel containing non-toxic, safer alternatives.



NAVIGATING REACH

On 1 June 2007, the new EU legislation on chemicals called REACH entered into force. REACH stands for Registration, Evaluation, Authorisation and restriction of CHemicals. The REACH regulation sets out a new approach for the control of the manufacture, import and use of chemicals in the EU. It replaces the previous flawed European system that was based on a patchwork of different Directives and Regulations developed since 1967, largely in response to scandals, and unable to kick-start preventive action.

17th May 2004 - BRUSSELS, BELG IJM. Greenpeace activists reconstruct a medieval court case with a Greenpeace 'Jacques Chirac' and a toxic Mickey Mouse 'Chemickey' - awaiting his fate on the gallows, while straddling one barrel containing consumer products known to contain harmful chemicals and the other barrel containing non-toxic, safer alternatives.

INTRODUCTION

REACH aims to address the crucial flaws of the previous EU system, notably:

- The lack of information about the impacts of the majority of chemicals in use on human health and the environment;
- Too slow progress on the identification and assessment of hazardous chemicals, and
- Insufficient regulatory actions on the replacement of hazardous chemicals.

REACH also sets up a body to oversee the safe management of chemicals – the European Chemicals Agency (ECHA), (hereafter called “the Agency”) - which is based in Helsinki, Finland.

New chemical legislation was long overdue, as evidence of the failings of the previous system became more and more blatant. However, the final result is not quite the robust and comprehensive REACH that was initially expected.

2.1 What was gained?

REACH represents a paradigm shift in chemical legislation.

- The chemical industry is now obliged to provide basic health and safety information for all chemicals produced or marketed in quantities over 1 tonne a year per importer or producer, before placing them on the market (“no data, no market” principle). Under the previous system public authorities had to first prove a chemical was harmful before being able to regulate it.
- It also sets up a system for better control of “substances of very high concern” such as those that accumulate in the environment and our bodies, cause cancer, are toxic to reproduction or alter genes, and substances that interfere with the hormone system. REACH will require some of these substances to be substituted with safer alternatives, whenever these alternatives become available.
- Under new provisions for increased access to information, companies using chemicals but also retailers, brands and consumers, now have the right to obtain information on whether very hazardous chemicals are present in products they buy.

2.2 Loopholes and flaws

But the regulation is also inadequate in many ways; there are exemptions and loopholes for industry, it does not automatically require sufficient information for the majority of chemicals in use and postpones key decisions to future reviews. Some critical points are:

- Companies may be allowed to continue importing, producing and using many hazardous substances associated with cancer, birth defects, reproductive illnesses and hormonal imbalances, even when safer alternatives exist.
- REACH registration will only apply to 30,000 out of the over 100,000 chemicals known to be on the market today, that is, only to substances produced or imported in volumes over one tonne per year per producer or importer. In addition, only rudimentary information may be required for 60% of the 30,000 chemicals because of loopholes built into the system, although the authorities could request more. Information on these substances will very likely be insufficient to decide if a substance is hazardous or not.
- The decision on whether to always oblige industry to replace chemicals that can mimic hormones (so-called endocrine disruptors) with safer alternatives, whenever they exist, has been postponed to a future date.

2.3 What is still at stake?

A new era has begun with the adoption of REACH, and the rules have changed, but the battle to secure a shift to safer chemicals in our daily lives goes on. While this is the start of the most promising phase - the implementation - it is likely that some chemical producers will continue to try to escape from the new health and safety requirements.

The momentum of public attention and scrutiny must be maintained. NGOs at national and European level can influence the implementation and enforcement of the legislation by closely monitoring and exposing deficiencies in the activities of industry and the regulators. They also need to keep encouraging companies to substitute hazardous substances with safer alternatives. Many opportunities will also emerge to improve and consolidate REACH when it is revised, provided that the awareness of hazardous substances and the demand for safer chemicals remain high on the political agenda.

Despite its flaws, REACH nevertheless is currently the most comprehensive system world-wide for the regulation of chemicals. Any improvement on chemical safety in Europe - the largest chemical producing region in the world with 30% of global sales - will certainly benefit other regions. In particular, the increased public information related to the most hazardous chemicals and on chemical health and safety in general, will be of universal benefit and can be readily used by environmental and public interest groups to expose double standards and to request improved chemicals management in other regions outside of the EU.

REACH will not make noticeable changes in our daily lives overnight but the potential is there to make manufacturers, downstream users, brands and retailers more responsible and accountable for the safety of their products, to foster the replacement of some of the most hazardous chemicals with safer alternatives, and to continue raising awareness among the wider public to allow for more informed choices to be made at all levels.



New substances



REACH: WHAT ARE THE KEY ELEMENTS TO KNOW?

The former EU regulatory system for chemicals management distinguished between “existing”⁴ and “new substances”⁵. The regulatory measures and testing requirements were different for these two groups. Industry was not obliged to provide adequate health and safety data on those chemicals produced before 1981 (existing substances) unless public authorities requested them because they suspected a problem. Since 1981, industry has had to systematically provide health and safety information on “new chemicals”, but to date only around 1% of chemicals marketed are “new chemicals”.

REACH: WHAT ARE THE KEY ELEMENTS TO KNOW?

REACH creates a uniform system for the regulation of new and existing chemicals; the latter will be progressively phased into the system and are referred to as “phase-in” substances. However, as a result of a trade off - to finally get data on the thousands of “phase-in” chemicals - the health and safety testing requirements under REACH are less stringent than for “new substances” under the former regulation. In addition, the former legislation for new substances applied to substances produced in a volume of over 10kg per year per producer or importer, whereas REACH only requires the registration of substances produced or imported in quantities of over 1 tonne per year per producer or importer.

What chemicals are covered by REACH?

There are around 100,000 chemical substances known to be on the European market; REACH registration applies to 30,000 substances which are manufactured, imported, used as intermediates or placed on the market, on their own, in preparations (e.g. paints) or in articles (e.g. furniture), in quantities above 1 tonne per year. Both authorisation and restriction procedures can also apply to unregistered substances or those produced/imported below the 1 tonne limit.

.. and not covered by REACH?

There are some types of substances which are excluded from the scope of REACH. These include, for example, substances which are radioactive, subject to customs supervision or non-isolated intermediates. Waste is not regarded as a substance, preparation or an article under REACH. Polymers such as PVC plastic are currently exempt from registration and evaluation but a future review may lead to their inclusion. Some substances covered by other specific legislation are exempted from parts of REACH, for example:

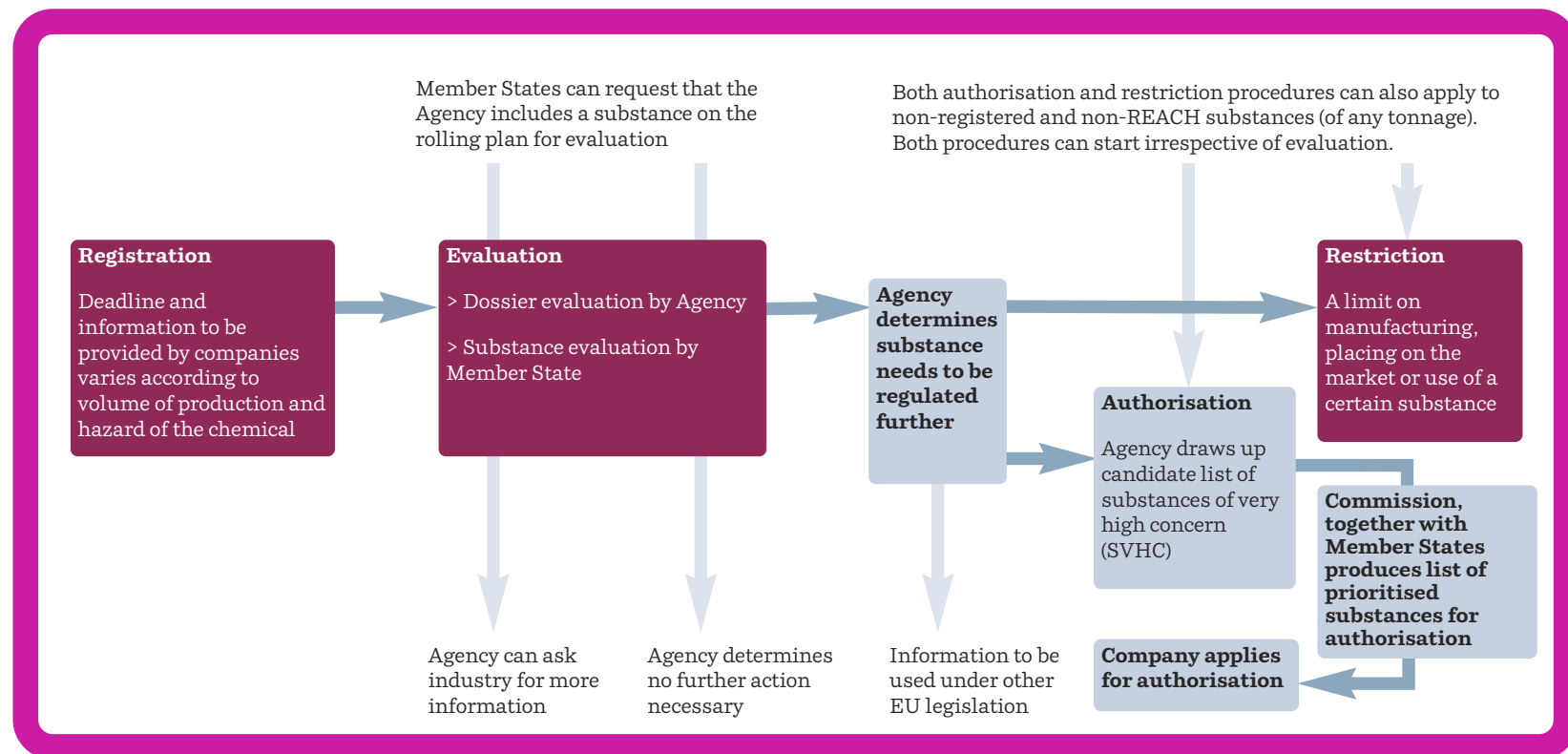
- Pesticides and biocides are considered as registered and exempt from authorisation, because these groups of dangerous substances are each covered by special laws⁶;
- Substances used for cosmetic products are exempted from certain requirements. In particular, authorisation for the use of substances in cosmetic products can only be required under REACH on the basis of environmental concerns and not on human health concerns, as these are covered by the EC Cosmetics Directive (76/768/EEC)⁷;
- Substances in food and medicinal products are exempt from registration, evaluation and authorisation as they are covered by other specific legislation.

The structure of REACH

REACH sets out four key procedures to manage chemicals; Registration, Evaluation, Authorisation and restriction of CHEMicals:

- Registration of basic information of substances produced in or imported to the EU over 1 tonne per year per producer or importer, to be submitted by companies;
- Evaluation of the registered (and other) information by the European Chemicals Agency and Member State authorities to determine hazards and risks;
- Authorisation requirements imposed on substances of very high concern, including in some cases their replacement with safer alternatives;
- Restriction of the uses of chemicals with properties of concern at Community level.

OVERVIEW OF REACH PROCEDURES



4 | Existing substances: all chemicals that were reported as being on the European Community market before 1 January 1981 (listed in the European Inventory of Existing Commercial Chemical Substances – EINECS)

5 | New substances: chemicals introduced to the market after 1981.

6 | The Pesticides Action Network Europe can be contacted for further information about pesticides and biocides, see: www.pan-europe.info

7 | See: Greenpeace International (2005), An investigation of chemicals in 36 eaux de toilette and eaux de parfum, February 2005. See: <http://www.greenpeace.org/international/press/reports/perfume-an-investigation-of>, and Peters, Ruud J.B. (2005), Phthalates and Artificial Musks in Perfumes, TNO Environment and Geosciences, R 2005/011. January 2005, report for Greenpeace Netherlands. See: <http://www.greenpeace.org/international/press/reports/phthalates-and-artificial-musk>. Also see these websites about cosmetics from various NGOs: <http://www.wen.org.uk/health/Reports/Prettynasty.pdf>, <http://www.env-health.org/IMG/pdf/UNISONleaflet06.pdf>, http://www.wecf.de/cms/publications/2006/women_toxic.php

3.1 REGISTRATION

REACH places the main responsibility for chemical safety onto the chemical producer or importer who has to generate the specific health and safety information about the substances it manufactures and/or puts on the market. Previously, the burden of proof was on the authorities which had to prove that chemicals might harm health and the environment before they could restrict them. Now REACH will apply the “no data, no market” principle which requires industry to provide health and safety data on chemicals they want to start or continue marketing in Europe and to show how they can be used safely.

Registration requires manufacturers and importers to provide specific information on their substances and to use that data to manage them safely. There is a general obligation for manufacturers and importers of substances to submit a registration dossier to the Agency for each substance manufactured or imported in quantities of 1 tonne or more per year. For chemicals produced or imported in quantities above 10 tonnes per year, a Chemical Safety Assessment and documentation in a Chemical Safety Report is

required. Failure to register means that the substance is not allowed to be manufactured, imported or placed on the EU market. REACH provides for a phase-in period of 11 years for the existing chemicals produced or marketed before 1981 (phase-in substances) to be entered into the system. This means that many of the substances covered by REACH will not be registered until 2018.

3.1.1 Health and safety data and registration

The registration requirements depend on the quantities involved⁸ and the properties of the substances, following the rule of thumb that “the higher the volume, the more data required, the sooner the registration” (see section 5.3).

By 1 January 2009 the Agency shall publish on its website a list of all phase-in substances and their registration deadlines (Article 28.4). Third parties (including NGOs) may submit information on those substances, which the Agency shall consider during the evaluation process (Article 41.6).

8 | This is the tonnage produced or imported per producer/importer. Annexes III to X of REACH set out the information requirements according to the tonnage band. See also section 5.3 of this publication.

9 | See <http://ec.europa.eu/echa/>

10 | In application of Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents.

Access to information

The general health and safety information of registered chemicals will be publicly available on the Agency’s website⁹ (Article 119), which will empower NGOs, progressive businesses, and retailers from any country in the world to get information about specific chemicals.

Other information may be requested from the Agency under EU laws on public access to information¹⁰. However, Article 118 of REACH lists a whole series of information which is deemed to undermine the protection of commercial interests of the industry concerned, and will therefore not be disclosed. Article 119.2 lists information that can be claimed confidential under certain circumstances. In this case, it will be up to the Agency to decide whether to uphold or reject industry’s demand for confidentiality. At the same time, NGOs and others may file a complaint to the Ombudsman against any decisions from the Agency to refuse access to information.

REACH also provides for the possibility of special access to confidential information for authorities of non-EU countries or international organisations (Article 120), who might be interested in sharing some data with the EU.



ALERT! IMPROVEMENT NEEDED: CHEMICAL SAFETY REPORT FOR LOW TONNAGE SUBSTANCES

The chemical industry lobbied to water down the registration requirements and managed to introduce less demanding provisions. As a result, companies may only have to provide extremely limited safety data for the registration of substances produced or imported between 1 and 10 tonnes per year; this is about 17,500 substances, almost 60% of the substances falling under REACH. Basic safety information may only have to be provided for about 10 to 30% of these low volume substances that meet certain criteria (Annex III). For the remainder, companies will have to submit only “available” data, which might not be sufficient to classify a substance as hazardous or not. Unless the authorities request more information, companies might not be able to identify whether a substance is acutely toxic or say whether it decomposes in the environment.

Neither the producer nor the authorities will have to carry out a risk assessment (in REACH this is called Chemical Safety Assessment – CSA, which is documented in the Chemical Safety Report - CSR) for substances in the 1-10 tonnage band. The obligation for a CSA starts only at 10 tonne per year and obliges the company to assess the characteristics of the chemical, its hazard to human health and the environment, and whether it is persistent and likely to build up in the food chain (bioaccumulates). At this point companies scrutinize hazards and exposure and commit formally to control the risk and describe risk reduction measures. The lack of a CSA/CSR for substances produced between 1 and 10 tonnes per year is a serious shortcoming that the coalition of NGOs and the trade unions hope to amend in an upcoming revision.

Opportunities to extend the risk assessment requirements

By 1 June 2014, the Commission shall carry out a review on whether or not to extend the requirement for a risk assessment undertaken by the producer (CSR) to substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction produced or imported in quantities under 10 tonnes;

By 2019, the Commission shall review the producer's obligation to carry out a risk assessment (CSR) and can propose to extend it to other substances not covered by this obligation.

It will therefore be important for NGOs to prepare to advocate again that companies should be required to submit a CSR for substances currently not covered by this obligation. This demand has also been voiced by trade unions and in the future downstream users of chemicals might be interested in supporting it, in order to limit their own liability.

The Agency is responsible for managing all registrations. The first step is an automated “completeness check” to verify that all of the required information elements are present in the dossier. However, the Agency does not necessarily check the quality and relevance of the information supplied. NGOs had asked that companies should commission an independent quality check of their registration dossiers to ensure the good quality of the information up-loaded into the system. Although well founded and despite precedents in other fields such as finance management existing in the EU, this demand has not survived the negotiations.

If the registration is not rejected within a set deadline, then the registrant may begin (for non phase-in/new substances) or continue (for phase in/old substances) to manufacture the substance or import it into the EU. The quality of the information submitted may be checked in the evaluation process (see section 3.2). The NGOs will monitor this process to ensure that the Management Board of the Agency allocates sufficient resources to this important task so that it will succeed in practice.

3.1.2 Substances in articles

To regulate substances in articles, REACH distinguishes between two types:

- articles which contain substances that are intended to be released
- articles in which substances of very high concern are present

REACH requires a registration for substances that are contained in articles and are intended to be released during normal and reasonably foreseeable conditions of use (e.g. scented candles). These substances have to be registered if they are contained in the articles above 1 tonne per producer or importer per year (Article 7.1).

If substances of very high concern are present in articles above a certain concentration limit¹¹, REACH requires those substances to be notified to the Agency (Article 7.2), except where exposure to humans and the environment can be excluded during normal conditions of use, including disposal (Article 7.3). In such cases safety instructions should be provided and information also be made

available to consumers on request. Examples of such substances in articles that would have to be notified include the varnish on a wooden table.

Discussions are still taking place between the Commission, the Member States, industry and the NGOs regarding the application of the 0.1% threshold for articles made of different homogenous parts. For example, in running shoes where the lining can be distinguished from the rest of the shoe, it could make a real difference whether the concentration of a dyestuff in the lining is calculated in relation to the lining only or in relation to the whole shoe. This problem is addressed in a non-binding guidance document which is currently being finalised.

As a safety net, the Agency can require the registration of any substance present in an article at any time, when it considers that its release could pose a risk to human health or the environment, provided that the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year (Article 7.5).

11 | of 0.1% weight by weight and produced or imported in quantities above 1 tonne per producer or importer per year, Article 7.2.

Opportunity to effect a change: right to know about chemicals of very high concern in consumer products

Consumers are entitled to information about the presence of “substances of very high concern”¹² in articles bought in the EU. Suppliers of articles containing these substances are obliged to respond to a consumer’s request to inform them about the presence of such substances in the article and to provide sufficient information to allow safe use of the article - as a minimum the name of the substance(s). This information is to be provided free of charge within 45 days (Article 33) (see section 5.4 for a sample letter to request information). This right to know will only start to apply when the substance concerned has been put on the candidate list according to Article 59.1 (see section 3.3). This is expected in autumn 2008.

In addition, REACH will require suppliers to inform retailers of articles about the presence of substances of very high concern in the articles they supply them with and the necessary information to allow the safe use of that article (Article 33).

Consumer organisations and citizens can use these provisions as a tool to get retailers and manufacturers to reveal the presence of chemicals of very high concern in consumer products. This in turn will stimulate retailers to give preference to safer products and manufacturers to seek and convert to safer alternatives. Chemicals of very high concern have been detected in many consumer products including children’s toys, printed T shirts, household products, sport shoes, cosmetics, baby body care products, etc.

For more details see:

<http://www.greenpeace.org/raw/content/international/press/reports/chemical-home-company-progress.pdf>

http://www.foeeurope.org/publications/2006/right_to_know.pdf



12 | i.e. substances that cause cancer, are toxic to reproduction or alter genes, substances which interfere with the hormone system, substances which are persistent and bio-accumulate and substances that give rise to equivalent concern

3.2 EVALUATION

During the evaluation process, the Agency in co-operation with the Member States' Competent Authorities will look in more detail at some of the registration dossiers and at substances of concern.

3.2.1 Dossier and substance evaluation

There are two types of evaluation with different aims: dossier evaluation and substance evaluation.

For the dossier evaluation, the Agency checks:

- if the registration dossier complies with the registration requirements. As a minimum, 5% of dossiers should be checked for each tonnage band;
- the testing proposals submitted as part of the registration, before the tests are carried out, in order to prevent unnecessary animal testing. The Agency will also invite third parties to submit information that would help to avoid vertebrate testing.

For the substance evaluation, the Agency, in co-ordination with the Competent Authorities of the Member States, may clarify suspicions of risks to human health or the environment by requesting further information from the registrant (see section 3.2.2).

Safety data and animal testing

REACH makes data sharing on animal test results compulsory and prescribes the use of alternative non-animal methods wherever possible. As part of the evaluation process the proposals for animal testing made by industry will be examined with the aim of preventing unnecessary testing. The legislation specifically states that “testing on vertebrate animals [...] shall be undertaken only as a last resort” and that the tests used are to be revised “in particular to refine, reduce or replace animal testing”. In particular the safety data that will become publicly available will prevent other producers and importers from carrying out that same test again in the EU and hopefully also in other parts of the world. When the generation of new data cannot be avoided, compliance with the rules of Good Laboratory Practice (GLP) will ensure world-wide acceptance of the results and thereby help to avoid test-repetition.

A position paper by the UK Government¹³ states that REACH “will represent a substantial improvement over the current methods of chemical regulation being faster, simpler and more efficient hence necessitating less animal testing for each chemical registered.”

3.2.2 When will substances be examined?

In cooperation with the Member States the Agency will develop guidance on the prioritisation of substances for further evaluation. It will also prepare a draft Community Rolling Action Plan (CRAP) covering a three year period and specifying substances to be evaluated each year. Criteria to prioritise substances for evaluation will include information on hazard, exposure and tonnage of production of the substance (Article 44). The first draft rolling action plan will be submitted to the Member States by 1 December 2011; the Agency will adopt the final version on the basis of an opinion from its Member State Committee and will publish it on their web site¹⁴. The plan will indicate which Member State is to carry out each evaluation.

In addition, any individual Member State may notify the Agency at any time of a substance not found on the rolling action plan, whenever it possesses information which suggests that the substance should be a priority for evaluation. The Agency shall then decide whether to add this substance to the rolling action plan on the basis of an opinion from its Member State Committee. If the substance is added to the plan, the proposing Member State, or another Member State who agrees, will evaluate that substance.

Any draft decision prepared by the Member State Competent Authority requesting further information on a substance must either be accepted by all other Member States, in which case the Agency takes the decision, or if an agreement cannot be reached the Commission takes the final decision.

Evaluation may lead the authorities to the conclusion that action needs to be taken under the restriction or authorisation procedures, or that information needs to be passed on to other authorities responsible for other relevant legislation.

Opportunity: Speed up the process!

Individual Member States can take the initiative and focus attention on a substance where new information has identified an emerging concern, by requesting an evaluation.

This can also be used as a means of overcoming the slow and somewhat random process of registration and its quality check as, in principle, all registration dossiers for the same substance and its breakdown products will be assessed together.

It will be important for NGOs to work with Member State authorities and provide them with information, literature studies and their own data to argue for prioritising certain substances under the “substance evaluation” process.



October 2002, Greenpeace. Explaining the testing of house dust at the home of Anita Roddick, Bodyshop founder. Results show how many toxic chemicals could be lurking in the home. These chemicals are in everyday consumer products. © greenpeace/robinson.

13 | Position Paper by the UK government “On REACH and Animal Testing”
Department for Environment, Food and Rural Affairs, May 2005

14 | See: <http://ec.europa.eu/echa/>

3.3 AUTHORISATION

Companies that wish to continue to produce or use chemicals that belong to a group of particularly harmful substances, have to apply for a special authorisation to be allowed to continue with specific uses of these hazardous chemicals in the future.

3.3.1 Chemicals of very high concern in the spotlight

The authorisation requirements apply to the so called “substances of very high concern” (SVHC). These are substances which fall into one of these classifications/categories (Article 57):

- Carcinogens (cause cancer), mutagens (cause gene mutations), or toxic to reproduction (CMR category 1 and 2),
- Persistent (degrade slowly or do not break down at all), bio-accumulative (accumulate in human bodies and the environment) and toxic (PBT)
- very Persistent and very Bio-accumulative (vPvB), or
- Identified from scientific evidence as causing probable serious effects to humans or the environment equivalent¹⁵ to those above on a case by case basis, for instance substances that interfere with the hormone system.

Opportunity: Ensuring PBT chemicals will be identified

The criteria for identifying persistent and bioaccumulative substances (PBTs), which will be subject to authorisation, will be reviewed by December 2008.

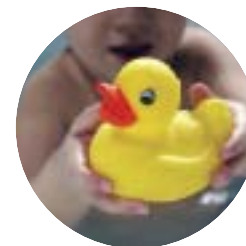
NGOs will advocate that these criteria should take into account the situation in the real world and should include all important PBTs or chemicals with PBT like properties. Currently even many internationally recognised PB(T)s - including some proposed Persistent Organic Pollutants (POPs)¹⁶ - will not meet the Annex XIII criteria, because of the restricted number of test methods that are foreseen.

15 | The latter point could also include neurotoxic and immunotoxic chemicals. Neurotoxic chemicals affect the nervous system and immunotoxic chemicals hamper the immune system, both could potentially not only be damaging for human health but also affect wildlife.

16 | The Stockholm Convention on Persistent Organic Pollutants (POPs) was adopted on 23 May 2001, under the auspices of the United Nations Environment Programme (UNEP). 12 POPs have been given priority: the production and use of existing intentional POPs listed in Annex A are to be prohibited/eliminated EXCEPT as allowed by Annex A, releases of other by-product POPs are to be minimised. New chemicals with POPs characteristics are also to be banned, once included in the Convention.

17 | For more details see: Fragile: Our reproductive health and chemical exposure, Greenpeace, May 2006. <http://www.greenpeace.org/international/press/reports/fragile-our-reproductive-health>

18 | OSPAR Commission for the Protection of the Marine Environment of the Northeast Atlantic: <http://www.ospar.org>. The Contracting Parties to the Oslo and Paris Conventions are Belgium, Denmark, the European Union, Finland, France, Germany, Iceland, Ireland, the Netherlands, Norway, Portugal, Spain, Sweden, and the UK.



Chemicals the NGOs are concerned about

The candidate list of SVHC will be drawn up by the newly created European Chemicals Agency in Helsinki. Campaigns and product testing by the NGOs have focused on a number of substances whose characteristics pose special concern, for example¹⁷:

Phthalates: used in many PVC products (eg vinyl floor tiles, toys), glues and inks and as additives in cosmetics and toiletries. A number of phthalates are known or suspected hormone disruptors, impacting in particular on reproductive development in animals. Some are associated with liver, kidney and testicular damage.

Alkylphenols and derivatives: used as industrial detergents, as additives in certain pesticide formulations and in some paints and plastics. They are considered hormone disruptors primarily because of their oestrogen-mimicking properties.

Artificial musks: fragrance enhancers added to many products like perfumes, cosmetics and laundry detergents. The commonly used polycyclic musks are persistent chemicals which accumulate in the food chain; they may be capable of interfering with hormonal systems in fish, amphibians and mammals.

Triclosan: an anti-bacterial chemical which is added to a wide range of products, including washing-up liquids, liquid soaps, mouthwashes, dishcloths and chopping boards. Triclosan and its breakdown product methyltriclosan have been detected as contaminants in the environment and triclosan has been found in human breast milk.

Alkyltin compounds/organotin compounds: used as anti-bacterial agents and catalysts in the production of some plastics, and as additives in some PVC and packaging materials. They are persistent and bio-accumulative and have been reported to be toxic to development and immune systems in animals.

Bisphenol A: used in the manufacture of linings for some food cans and lids, and in the manufacture of polycarbonate plastic bottles. It has shown hormone disrupting characteristics and is suspected of affecting female and male reproductive development.

Brominated flame retardants (BFRs): used in furniture fabrics and plastics (e.g. in personal computers) to counteract the spread of fires. Most commonly used BFRs are persistent and accumulate in the food chain, and several have been identified as hormone disruptors. Exposure to PBDEs in the womb has been associated with abnormal skeletal and brain development in animals.

Perfluorinated Chemicals: used to make stain-repellent coatings in carpets, textiles and paints, non-stick coatings on saucepans and the insides of fast food and microwave popcorn wrappings. PFCs persist in the environment and can build up in soils and body tissues of animals. Some are known to be toxic to animals, harming reproductive success in freshwater invertebrates and damaging the liver in fish and mammals. They may also increase uptake and toxicity of other toxic chemicals present.

Many of these chemicals have already been highlighted on the List of Chemicals for Priority Action (1998 and updated since) by the OSPAR Commission¹⁸, which is supported by the EU.

See also:

Results from WWF bloodtesting of 3 generations of European families:
http://www.panda.org/about_wwf/where_we_work/europe/what_we_do/epo/news/index.cfm?uNewsID=23635

Consuming Chemicals - Hazardous chemicals in house dust as an indicator of chemical exposure in the home, Greenpeace, 2003
<http://www.greenpeace.org/international/pres/s/reports/consuming-chemicals-hazardou>

Chemicals do not have to be registered in order to enter the authorisation procedure. The authorisation procedure may cover any substance identified as being of very high concern regardless of the volume of production or import. This means also that the use of small quantities of those substances will need to be authorised. However, volume of production is one of the criteria for the prioritisation process in the authorisation system.

3.3.2 Understanding the authorisation procedure

The authorisation procedure consists of five main steps:

- 1** The Agency or any individual Member State may prepare a dossier (Annex XV) suggesting substances that scientifically speaking would belong to the above groups of substances of very high concern. The Agency will then publish these dossiers on its website and invite all interested parties (including NGOs) for comments within specified deadline. Once a substance is confirmed to be fulfilling the criteria of being a SVHC, the Agency shall include it in a list called the candidate list for eventual inclusion in the priority list for authorisation (Annex XIV) (Article 59). The first candidate list is expected in Autumn 2008.
- 2** The Agency then draws its draft recommendation for chemicals to be included in the list of priority substances subject to authorisation (Annex XIV) based on the candidate list. REACH specifies that substances which are persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB), those substances which have dispersive use or those which are produced in high volumes, will have priority for entering the authorisation system. The first recommendation should be published by the Agency by 1 June 2009 (Article 58.3). Before submitting it to the Commission for final approval, the draft recommendation will be published by the Agency on its website¹⁹ and all interested parties will be invited to submit comments to the Agency within three months of the date of publication (Article 58). The Agency shall make further recommendations at least every two years for new chemicals to be added to the Annex XIV list.
- 3** The Commission, together with the Member States²⁰, take the final decision on which substances will be included in the authorisation system (Annex XIV), whether specific uses of those substances should be exempted and set the deadlines within which companies must apply for an authorisation if they want to continue using them.
- 4** Once a substance is included in Annex XIV, those using or making available such a substance will need to apply for an authorisation for each use of the substance within a set date, and analyse possible safer alternatives. If this analysis shows that suitable alternatives are available, then the applicant must also include a substitution plan, including timelines on how they intend to substitute the SVHC with a safer alternative.

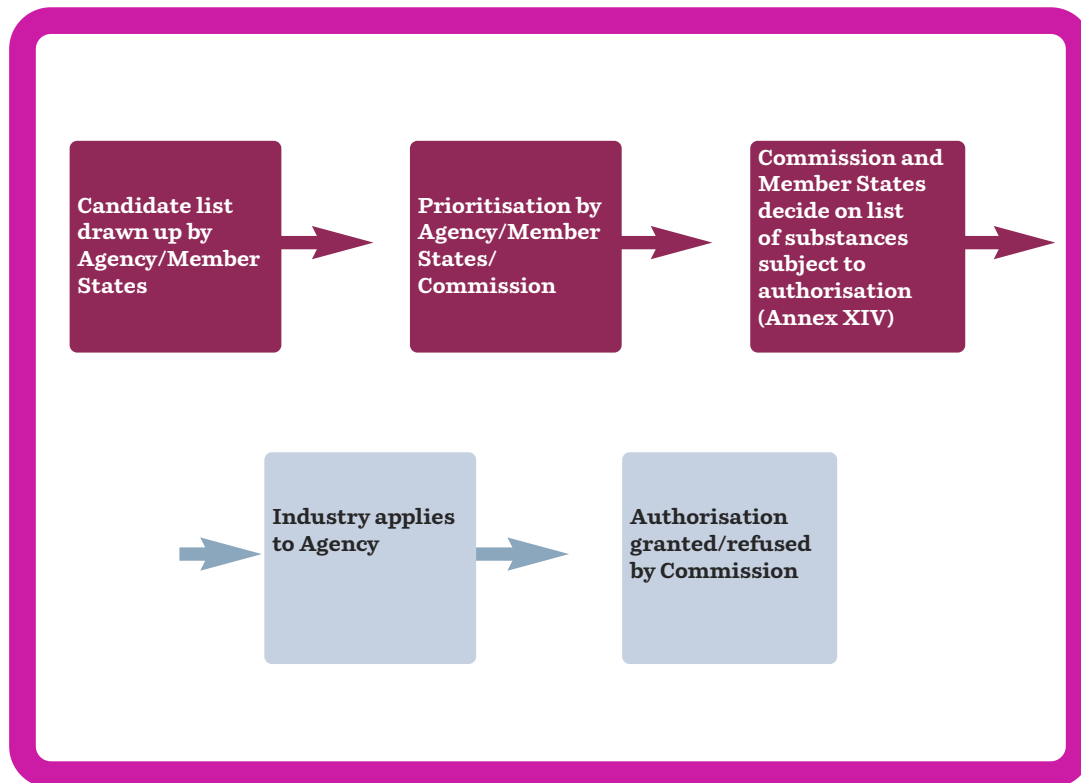
19 | See: <http://ec.europa.eu/echa/>

20 | Committee procedures attended by Member States experts and chaired by the Commission (the so-called "comitology procedure") will take the final decision on which substances will be included in Annex XIV. For more information see: http://europa.eu/scadplus/glossary/comitology_en.htm

OVERVIEW OF AUTHORISATION PROCEDURE

5 There is then a two-route procedure for the Commission to decide²¹ whether to grant an authorisation or not, depending on the chemical's hazard:

- *The substitution route:* Authorisation for PBT and vPvB and non threshold chemicals may be granted only if the socio-economic benefits outweigh the risks to human health and the environment and if there is no safer alternative available.
- *The “adequate control” route:* Authorisation for CMRs and substances of equivalent concern shall be granted if the applicant can demonstrate that a “safe threshold” below which no serious adverse effects can be established and that the risk from the use of the substance is “adequately controlled”. If no safe threshold can be established, or if the company cannot prove that it “adequately controls” the substance, then the CMR or substance of equivalent concern takes the “substitution route” (see above).



21 | The Commission's decision will be informed by the Agency's Socio Economic Analysis (SEA) Committee as well as by the Risk Assessment (RA) Committee, which will examine the different parts of the authorisation application and produce opinions. See section 3.5.2. P 29.

Opportunity: Promote Substitution!

The candidate list and Annex XIV represent very important reference tools to promote substitution without waiting for the Commission to decide whether or not to grant an authorisation.

Both lists are an incentive for companies who have been using these particularly harmful chemicals to increase their efforts to look for safer chemicals or technologies. They will also be important reference lists for consumers and retailers to exert their right to know whether such substances are present in the products they buy and to exert pressure on companies to offer products free of these substances.

Finally, campaigners outside the EU could use these lists to drive substitution forward and call for better standards, legislation or practices in their country or their region, as well as to expose double standards by multinational companies, some of which may market hazardous substances in non-EU countries but supply safer alternatives only in the EU.

For examples for substitution see also:
http://www.ecocouncil.dk/download/subst_uk.pdf

Decision to authorise: Substitution versus Adequate Control

Given the very serious and irreversible effects that substances of very high concern can have on human health and the environment, the coalition of NGOs advocated to change the initial Commission proposal to incorporate the substitution principle so that no authorisation would be granted where a suitable safer alternative is available to replace a chemical of very high concern, leading to the substance being phased out.

NGOs have been successful in making sure that the substitution principle applies effectively to PBTs, vPvBs and non threshold chemicals (CMRs and those of equivalent concern) for which a “safe level” cannot be defined. However, other substances of very high concern will be allowed to remain on the market, even when safer alternatives are available. In the future, industry might try to obtain authorisation for more non threshold substances by simply showing “adequate control”, as the preamble of REACH states that “methodologies to establish threshold for carcinogenic and mutagenic substances may be developed”. Unfortunately the vague definitions in REACH leave plenty of room for misinterpretation. To counteract that, continuous NGO-involvement is required, in the form of public scrutiny, pressure and highlighting of safer alternatives.

3.3.3 Endocrine disrupting chemicals

Endocrine disrupting chemicals (EDCs) are among the substances that should fall under the authorisation process as “substances of equivalent concern”, which will be identified on a case by case basis. These are chemicals which interfere with the hormonal systems of people and wildlife, in particular with the thyroid hormones and sex hormones. Their control under REACH falls short on two counts:

- the level of evidence of “probable serious effects” on health or the environment, which is required to qualify for the candidate list for authorisation as a SVHC, could be interpreted too narrowly; NGOs need to watch in particular that the precautionary principle is properly applied.
- once substances qualify, decisions for their authorisation may be taken according to the “adequate control route” and not the “substitution route”. A revision in 2013 should make sure that EDCs always take the substitution route.

Opportunity: Substitution for hormone-mimicking toxics

Endocrine (hormone) disrupting chemicals (EDCs) were almost included in the “substitution route of authorisation” following a proposal from the Council and strong support from some political groups in the European Parliament. However, fierce debates in the last hours of trade off between the Council of Ministers, the European Commission and the European Parliament led them to postpone the decision to a review planned for 2013 when hormone disrupting chemicals could be excluded from the adequate control route.

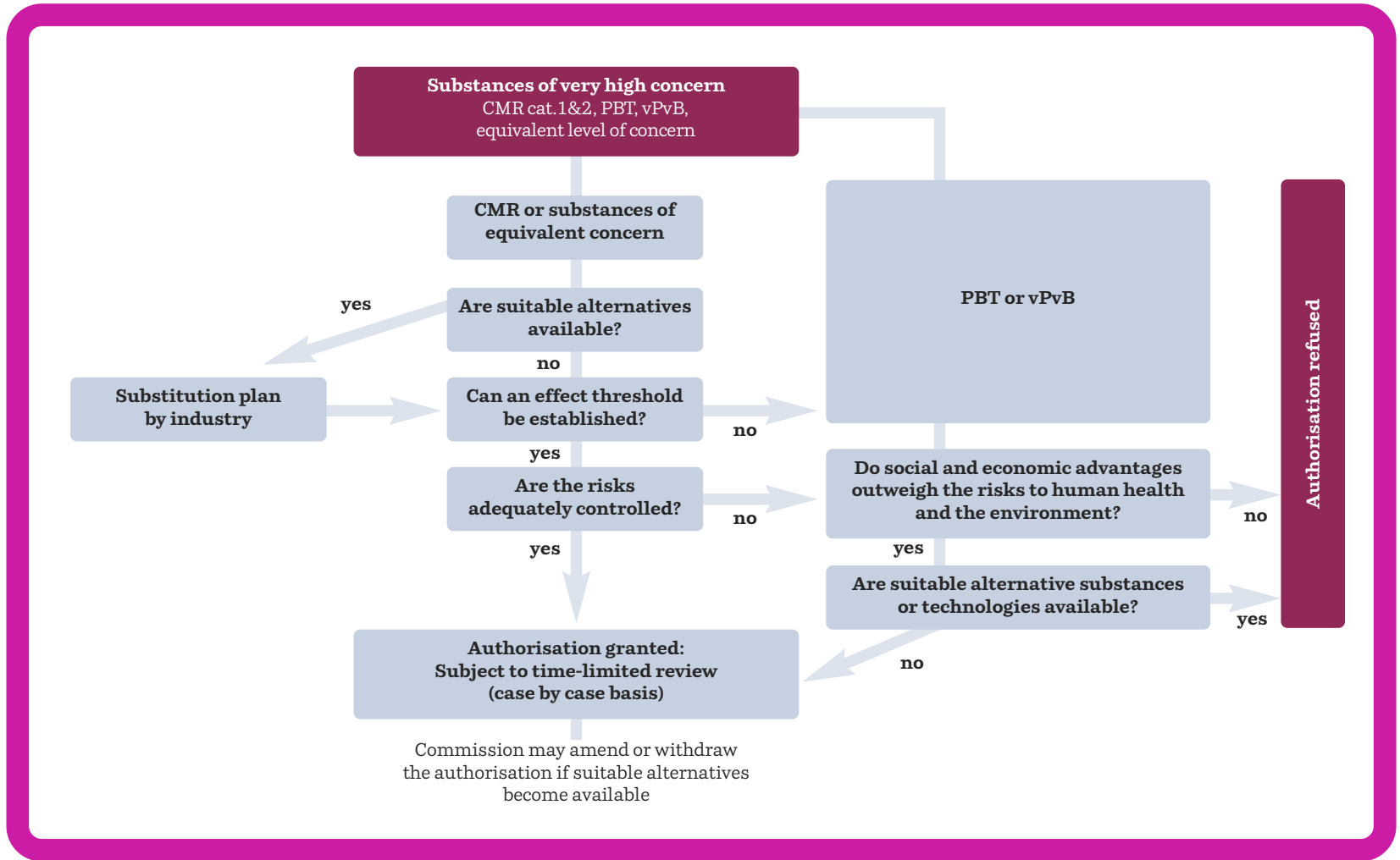
There is increasing scientific evidence supporting the premise that endocrine disruptors do not have safe thresholds, as very tiny amounts have been linked to negative effects. It will be crucial for NGOs

and the scientific community to put pressure on the policy-makers to act upon the scientific data in this critical revision of REACH. If EDCs are excluded from the “adequate control” route, no authorisation would be granted for an EDC if a suitable safer alternative is available to replace it.

To this end, NGOs need to continue to gather scientific evidence about the impact of endocrine disrupting chemicals as well as possibilities for substitution, working with scientists and progressive business and informing the public about how these substances may affect men, women and children.

See also: Environmental contaminants and breast cancer: the growing concerns about endocrine disrupting chemicals
http://www.panda.org/about_wwf/where_we_work/europe/what_we_do/epo/initiatives/chemicals/index.cfm?uNewsID=83820







ALERT! THE NEED TO LIMIT THE "ADEQUATE CONTROL" ROUTE

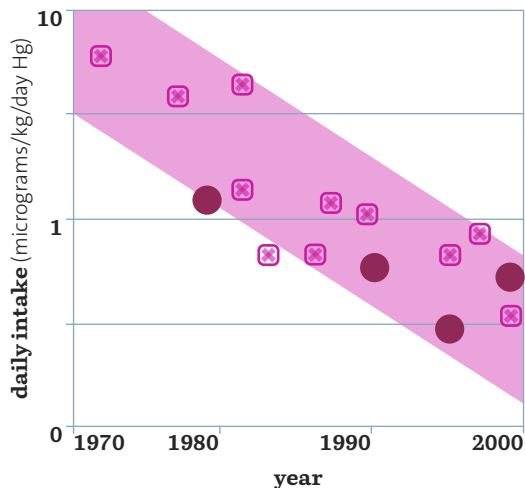
Companies will try to argue that they "adequately control" the use of a substance of very high concern and thus ask for this use to be authorised. NGOs continue to point out that the precautionary principle should be applied, especially where there are safer alternatives available and the use of hazardous chemicals is therefore unnecessary.

The concept of "adequate control" is based on the assumption that there is an acceptable level of risk, or a "safe threshold" below which adverse effects would not occur, and that regulators together with industry can determine acceptable levels of exposure from these risk calculations. It has proved impossible to use substances of very high concern completely safely in all circumstances, especially when the whole life cycle is considered. The mere fact that these chemicals can be found in remote areas of the world, in the bodies of polar bears, seals, and most importantly humans, clearly illustrates this point. Moreover, thresholds never provide protection in a real world situation, with different chemical tolerances, new emerging information on chemical effects at low doses, exposure of infants even in prenatal development and our constant exposure to a cocktail of hazardous chemicals.

History shows that thresholds drop over time as more information about the hazards becomes available and thresholds are lowered accordingly, a fact that illustrates how flawed the idea of "adequate control" is. The case of mercury illustrates this very clearly.

This graph displays the apparent toxic threshold for mercury as it was identified at various points in time over the past three decades. It illustrates the tendency for apparent toxic thresholds to decline with advancing knowledge²².

Mercury Declining Threshold of Harm



- ✕ level associated with harmful effect
- regulatory standard (maximum safe exposure or high end exposure from allowed fish contamination)

22 | Schettler, T., Stein, J., Reich, F., Valenti, M., Wallinga, D.: In Harm's way, Greater Boston Physicians for Social Responsibility, prepared for a Joint Project with Clean Water Fund, Cambridge MA USA, May 2000, p.24. See also: http://www.psr.org/site/DocServer/In_Harm_s_Way_complete.pdf?docID=661

A rather self-regulatory approach to substitution

Companies will have to provide substitution plans when a safer alternative is available on the EU market. However, as the companies themselves have to first identify those alternatives, they may choose to overlook or ignore them, maintain that they are technologically or financially unfeasible or claim, for instance, that they would not be able to source an alternative in their country. It is also important to note that the absence of an overall deadline for the phase out of authorised chemicals or a clear authorisation process undermines the credibility of this approach and could make it in effect voluntary.

Which chemicals could still be permitted under REACH even when safer alternatives exist?

A **phthalate called DEHP**, classified by the EU as Toxic to Reproduction (CMR), is widely used as a plasticiser (or softener) in consumer goods made of soft PVC (vinyl flooring, furnishings, clothing, surface coatings, medical devices, etc.) as well as in other dispersive applications. DEHP has been shown to pose significant risks to human health from direct exposure to products and through the environment.

As a CMR, the European Commission could permit its continued use if companies argue that DEHP will not cause harmful effects under certain levels of exposure. A number of studies have failed to identify any “safe” exposure level to DEHP with respect to reproductive toxicity. Other studies propose acceptable thresholds. The European Commission could then accept DEHP as a chemical which can be adequately controlled, despite the fact that such a decision would ignore the potential for more harmful effects when DEHP is in a mixture with other chemicals or on more vulnerable members of society, such as pregnant or breastfeeding women and infants.

In this scenario, a company seeking authorisation would need to present an analysis of alternatives. However, it is

possible that the analysis of alternatives would be no more than a paper exercise which could be filed away without consequence, at least until the authorisation comes up for review, since the product would be authorised in any case as able to be “adequately controlled”. Failing to identify “safer alternatives”, the company would not be required to present a substitution plan and thus would not have to use any of the available safer substitutes to DEHP, despite the fact that they already exist on the market. In this case, it will be up to the other interested (third) parties to present them.

The case of DEHP illustrates that, even where uses are widespread and dispersive, including the uses of high concentrations in consumer goods, and even if the use of suitable available alternatives would reduce the overall risks to human health and the environment and are technically and economically feasible for different uses, substitution would neither be required nor even encouraged. This will not ensure that such substances will be “progressively replaced by suitable safer alternative substances or technologies” even “where these are economically and technically feasible” (Article 55).

See: Fatal Flaws: Effect thresholds and “adequate control” of risks, Greenpeace, 2006 <http://www.greenpeace.org/raw/content/international/press/reports/effect-thresholds-and-adequat.pdf>

3.3.4 Time limits and reviews for authorised substances

Any decision to authorise a substance of very high concern will be subject to a time-limited review, determined on a case by-case-basis. A clear maximum validity for authorisation decisions would have been a better incentive to develop alternatives and foster innovation. An overall maximum time limit, as recommended by the NGOs, could have prevented endless discussion about the length and possible reviews of authorisation and created stronger incentives for research and investment in the development of safer alternatives.

In cases where there is a serious and immediate risk to human health or the environment, the Commission may suspend the authorisation, pending the review of the decision. In addition, authorisation may be reviewed at any time if:

- the circumstances of the original authorisation have changed so as to affect the risks to human health or the environment, or the socio-economic impact; or
- new information on possible safer alternative substances or technologies becomes available.

Substitution in Action

The Greenpeace report Safer Chemicals within REACH (February 2005) gives examples of leading manufacturers and retailers moving to phase out hazardous materials. These include Electrolux, Samsung, Sony, IKEA, NEC, Marks & Spencer, H&M, Laura Ashley, Skanska and Siemens among others. The report presents a large number of cases in which substitution has been carried out successfully, following a systematic approach to finding alternatives. This demonstrates that substitution is feasible and is already happening in the more progressive sectors of industry.

In addition, downstream users, retailers and industry sectors further down the product chain, such as waste water treatment facilities, expressed their concerns about the need to apply the precautionary principle and ensure a strong substitution principle, during the REACH negotiations.

Examples of specific steps that companies have taken to substitute hazardous substances²³ are given in the Greenpeace report “Cleaning up our Chemical Homes”:

<http://www.greenpeace.org/raw/content/international/press/reports/chemical-home-company-progress.pdf>.



13 December 2006 - STRASBOURG, FRANCE. Greenpeace displays toxic barrels, trees and banners outside meeting room of European Parliament.

23 | Specifically, substances identified on the OSPAR list of chemicals for priority action, extended to include all phthalates, synthetic musks, alkylphenols and PVC.

3.4. RESTRICTION

Chemicals do not have to be registered in order to be restricted. The restriction process can deal with any chemical, including those chemicals that are exempt from the registration process, and can also lead to action being taken on a “phase-in” substance that has not yet been registered. The restriction procedure therefore acts as a safety net to deal with a situation where a chemical has been identified as causing an unacceptable risk to humans or the environment and for which it is demonstrated that risks need to be addressed on European wide basis. REACH will bring an end to national restrictions as of 1 June 2013²⁴ but as a transitional measure until then, Member States are allowed to maintain any existing and more stringent restrictions provided that they have been adequately notified to the European Commission. By 1 June 2009, the Commission shall compile and publish an inventory of these restrictions.

The core of the restriction process is the preparation of a structured dossier by Member States or by the Agency on behalf of the Commission (Annex XV). The Restriction dossier – like the risk assessment in the previous system - will seek to demonstrate that a risk to human health or the environment is not adequately controlled and identify the most appropriate set of risk reduction measures. This dossier will then be discussed within the Agency committees and interested parties, including NGOs, will have an opportunity to comment on the Annex XV dossier(s) and/or submit socio-economic analysis or information within 6 months of the date it is published on the Agency’s website (Article 69.6.b). The Agency will also invite interested parties to comment on draft opinions from the Committee for Socio-Economic Analysis (Article 71.1). The Agency will set up and maintain a list of substances for which a dossier is planned or underway. The decisions will be taken by the Commission, together with the Member States.

24 | However, some national restrictions could be maintained or initiated under Article 95.5 of the EC Treaty, which allows Member States to introduce national provisions based on new scientific evidence on grounds of a problem specific to that Member State. This article overrides the REACH provisions. Also within REACH there is the safeguard clause (Article 129) which allows Member States to adopt safeguard measures on a provisional basis, to be approved/rejected by regulatory comitology procedure (Article 125).

25 | http://ec.europa.eu/echa/about/organisation/organigramme_en.html

3.5 ENFORCEMENT ISSUES

3.5.1 Main responsibilities and organisation of the European Chemicals Agency

The European Chemicals Agency (ECHA) will be the central body coordinating and supporting the registration, evaluation, authorisation and restriction procedures. It is located in Helsinki and is required to be operational as from 1 June 2008. Its tasks include providing scientific/technical advice and developing guidance and tools for registrants and Member State Competent Authorities.

The Agency is composed of several important bodies, which will meet in Helsinki to prepare opinions and decisions so that the above procedures can be carried out²⁵:

- a Management Board;
- a Member State Committee;
- a Committee on Risk Assessment (RA);
- a Committee on Socio-Economic Analysis (SEA);
- a Forum for Exchange of Information on Enforcement;
- a Board of Appeal that will consider appeals against the decisions of the Agency.

The Committees are composed of representatives of the Member States, including possibly their advisers on scientific, technical or regulatory matters, and additional invited experts. The Executive Director and representatives of the European Commission are entitled to attend all the Committee meetings as observers. Stakeholders, including NGOs, may also be invited to attend meetings as observers, at the request of Committee members or the Management Board.

The Agency's Management Board has the key responsibility for orchestrating the Committees and managing the Agency's activities, and consists of:

- one representative from each Member State with voting rights;
- two independent members with voting rights, nominated by the European Parliament;
- six members nominated by the European Commission, among which there is a representative from industry, from trade unions and from NGOs, each of the latter three with no voting rights.

The Management Board is responsible for critical decisions in relation to the work programme and the budget of the Agency.

3.5.2 NGOs' roles and representation

Monitoring and challenging the work of the Agency will be a key task for the NGOs. The European Commission has invited the coalition of health, environment and women's NGOs, together with European consumers, to be represented on the Management Board of the Agency. This representative has a four year mandate with no voting rights.

NGOs expect to also be invited to attend meetings of the Forum for Exchange of Information on Enforcement and different Committees (see above). The most important committee is the Member State Committee, where the draft opinions from the two expert committees (Committee for Risk Assessment and the Committee for Socio-Economic Analysis) will be discussed.

NGOs may be eligible to challenge the Agency's and/or Commission's final decisions if certain criteria are fulfilled²⁶. NGOs are unlikely to be eligible to appeal before the European Court of Justice against a decision of the Agency as the decision must be of direct and individual concern, but they can complain to the Ombudsman about the Agency and/or the Commission if they fail to act in accordance with the law, fail to respect the principles of good administration, or violate fundamental rights.

26 | Regulation (EC) N° 1367/2006 of the European Parliament and of the Council on the application of the provisions of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters to Community institutions and bodies entered into force on 28 September 2006. The "Aarhus Regulation" covers not only the institutions, but also bodies, offices or agencies established by, or on the basis of the EC Treaty. All those had until 28 June 2007 to adapt their internal procedures and practice to the provisions of the Regulation. See: <http://ec.europa.eu/environment/aarhus/>

3.6 TIMELINE OF REVIEWS AND REVISIONS OF REACH

3.5.3 Competent Authorities of the Member States

The role of the authorities at national level is to establish national helpdesks for industry and to take appropriate enforcement measures. Member States will carry out the evaluation work and in most cases will prepare proposals to subject substances to harmonised classification, restriction or authorisation.

Regarding the enforcement of the regulation, Member States are to adopt the necessary provisions on penalties for infringement of REACH before 1 December 2008 and to notify the Commission. Member State authorities will be supported in their efforts to enforce the legislation at national level by the Forum for Exchange of Information and Enforcement to be set up within the framework of the Agency (see Article 77.4 and Article 86). It would be desirable for the enforcement by Member States to be harmonised as far as possible in order to prevent industry from abusing weaker systems in certain Member States. For a list of Competent Authorities in EU Member States see section 5.5.

Many provisions of the regulation are due to be reviewed and revised in the forthcoming years, and will provide opportunities for REACH to be either improved or weakened. Some of these are explained in detail above. A full list which summarises the planned dates for reviews and revisions is below (Article 138).



WWF activists demonstrating for uncontaminated blood and stronger REACH (Brussels, 2004). © WWF-Canon/Andrew Kerr

27 | Polymers such as PVC are produced when monomers react and bind chemically to one another in long chains. Many different combinations of different monomers are possible and for the time being, monomers are registered only individually and not in reacted form. However, additives such as plasticizers that do not bind chemically into the polymers require registration.

REACH TIMELINE PROGRESS THROUGH EU LEGISLATIVE PROCESS

- 2007 1 June 2007 - REACH enters into force in all 27 Member States
- 2008 By June 2008 committees attended by representatives from EU Member States and chaired by the EU Commission (a procedure called “comitology”) will make important decisions on the criteria for establishing threshold concentrations for substances of very high concern and revising the list of substances exempted from the scope of the legislation.
- By December 2008 (again in comitology committees) review of: –
- the criteria for identifying substances that are Persistent, Bioaccumulative and Toxic (PBT) or that are Very Persistent and Very Bioaccumulative (vPvB) (Annex XIII)
 - criteria defining what constitutes adequate justification for avoiding to perform certain safety tests (Annex XI)
- 2010 December 2010 (after 3.5 years) – Deadline for registration of certain chemicals of very high concern and substances produced/imported in high volumes (above 1,000 tonnes per year)
- 2012 2012 (after 5 years) - General review under EU co-decision (a decision-making process where the European Parliament and the governments act as co-legislators) of: –
- the scope of the law (will add/delete chemicals to the list of substances covered by the legislation)
 - the information requirements for substances produced/imported between 1-10 tonnes per year
- 2013 2013 (after 6 years) - General review under EU co-decision – whether to require the substitution of substances that interfere with the hormone system (endocrine disruptors)
- June 2013 (after 6 years) – Deadline for registration of chemicals produced/imported in quantities between 100 and 1,000 tonnes per year
- 2014 2014 (after 7 years) - General review under EU co-decision – whether a Chemicals Safety Report (CSR) should be submitted for substances between under 10 tonnes meeting the criteria for classification as CMR cat 1 or 2.
- 2018 June 2018 (after 11 years) – registration of low volume chemicals between 1- 100 tonnes per year
- 2019 2019 (after 12 years) - General review under EU co-decision to decide whether or not to entitle consumers to information about further dangerous substances present in articles (e.g. allergens). Currently the duty to inform consumers upon request about substances in articles is limited to SVHC.
- 2019 (after 12 years) – The EU comitology committees will review the tests for reproductive toxicity
- 2019 (after 12 years) – General review under EU co-decision – whether a Chemical Safety Report (CSR) should be submitted for substances other than CMRs produced or imported under 10 tonnes per year or not subject to registration.

As well as the above, the Commission may present legislative proposals on the registration of polymers after it has published a report on the risks posed by polymers in comparison to other substances and assessed whether there is a need to register them. For the time being, monomers are registered separately²⁷.

3.7 IMPORTANT ISSUES NOT COVERED IN REACH



ALERT! DUTY OF CARE
COULD BE APPLIED
TOO LOOSELY

The first draft REACH proposal published for consultation in May 2003 included an article about “duty of care” that was then deleted in the final proposal. A recital mentioning collection and communication of available information is all that remains of the European Parliament’s demand from its first reading to adopt some legally-binding provisions, which were not agreed by the majority of the Council of Ministers. There are approximately 70,000 chemicals produced or imported in volumes below 1 tonne per year, for which REACH does not require any safety obligations. To fill these gaps NGOs, the European Trade Union Confederation and others had requested that REACH should include a legally-binding “duty of care” for all chemical producers, importers and users, making them responsible for the safety of their products. This provision was to require chemical manufacturers and importers to guarantee the safety of all their chemicals in all their uses, and to oblige them to make available, on request, sufficient supporting information. Such provisions would have simply codified existing voluntary programmes of the chemical industry such as Responsible Care.



ALERT! NANOPARTICLES

Despite the NGOs advocating that REACH should include a consideration of potentially adverse effects of nanoparticles on human health and the environment, legislators have opted to exclude the majority of engineered nanoparticles from the scope of the regulation. As some nanomaterials have different properties and pose a different risk to human health and the environment than conventional materials, they should be regarded as new substances and assessed separately from their larger counterparts. A limited number of nano-sized compounds are likely to be covered by the registration requirement - most as a “separate use” of their larger-sized counterparts (i.e. not

registered separately as a new chemical), but only if both forms are produced or imported by the same company or are part of the same supply chain. Most might never be registered as their tiny size and almost negligible tonnage mean that hardly any may be imported or produced at the REACH threshold quantity of one tonne or more per year.

There is no easy solution; due to the novel characteristics of nanomaterials, the current risk assessment methodologies (in particular toxicological and ecotoxicological methods) are widely seen as insufficient to assess risks associated with nanomaterials and will require considerable modification.

Opportunity: adding nanomaterials to the scope of the legislation. The NGOs will keep working to highlight the need to improve current legislation to control the risks and manage this rapidly expanding industrial sector. One of the windows of opportunity is the review of scope of the legislation as well as the review of information requirements for substances between 1 and 10 tonnes (both in 2012). However, this may be too late to start gathering data and limiting exposure to the rapidly increasing quantities of manufactured nanomaterials.

CONCLUSION

CONCLUSION

REACH is the most comprehensive and progressive chemicals legislation in the world, yet it still contains serious loopholes and legal uncertainties. It therefore represents work in progress. Effective and definitive improvements on the current situation are possible, but will largely depend on the tight scrutiny of its implementation at national and European level, the results of future reviews of key provisions and increasing market pressure for safer products. NGOs and citizens therefore need to focus both on **improving** the REACH legislation, and on **using** its provisions to ensure that hazardous chemicals will be phased out in the long-term.

4.1 PRIORITIES FOR IMPROVING REACH

Numerous critical and controversial aspects of the regulation will be subject to review and revision in the forthcoming years. These will include, among others, the review of criteria for identifying PBT and vPvB substances, the inclusion of endocrine disrupting chemicals in the substitution route and the extension of the consumer's right to know. These could present opportunities to improve certain aspects of REACH and re-open the debate.

NGOs will need to prepare strong scientific argumentation, campaign vis-à-vis decision-makers and mobilise the public throughout the EU to secure improvements in REACH. NGOs will certainly prepare for these reviews at the European level. The continuous involvement of organisations on national level both for liaising with national Competent Authorities and to maintain public awareness will also be key to such success.

The key battlegrounds for the future improvement of REACH are:

Ensuring that persistent and bio-accumulative substances will be identified

NGOs will need to advocate that the criteria for identifying persistent and bioaccumulative substances (PBTs) should take into account the situation in the real world and should include all important PBTs or chemicals with PBT like properties.

Endocrine Disruptors – a test for REACH's application of the Precautionary Principle

The uncertainty around the substitution provisions for endocrine disruptors (EDCs) is one of the key problems of REACH as it stands. The requirement to prove “probable serious effects” needs to be interpreted in light of the precautionary principle, enshrined by REACH.

The precautionary principle defended by the NGOs also has strong support within the scientific community. The Prague Declaration from May 2005²⁸ has been signed by over 100 international scientists working at the cutting edge of research into EDCs. It highlights the serious concerns about

endocrine disrupting chemicals. This Declaration presses for precautionary action and states, *“In view of the magnitude of the potential risks associated with endocrine disruptors, we strongly believe that scientific uncertainty should not delay precautionary action on reducing the exposures to and the risks from endocrine disruptors”*²⁹.

When the Commission carries out its review to consider the inclusion of EDCs in the substitution route for authorisation, NGOs, together with scientists should prepare for this crucial opportunity to get these provisions right.

NGOs should organise campaigns to call on Member States and the European Commission to ensure that chemicals with endocrine disrupting properties are brought under prior authorisation when sufficient scientific evidence already exists showing they might contribute to serious effects on humans or wildlife.

28 | See <http://www.edenresearch.info/declaration.html>

29 | See WWF briefing on low doses, http://assets.panda.org/downloads/wwf_briefing_on_low_doses_final.pdf

A “safe threshold” for CMR substances?

Chemicals that cause cancer, genetic mutations and/or are toxic to reproduction (CMR), could potentially be authorised even if safer alternatives are available, under the misleading concept of “adequate control”. This is of great concern to the NGOs. The concept of “adequate control” is based on the idea of a “safe threshold”, below which there would be no risk of harm. However, scientific assessments of these thresholds normally do not take into account all of the possible effects, interactions with other chemicals, or the varying sensitivities of the people exposed, for example, pregnant women and infants. Worse still, this flawed concept could be extended to cover even more CMR substances, under a provision in REACH to develop new methodologies for determining a safe threshold for CMRs with no previously established threshold.

It will therefore be necessary to counteract any attempts by the chemical industry to limit the application of the substitution principle as much as possible. NGOs will need to continue working with the scientific community to show that the “safe threshold” concept for substances of very high concern is flawed and exposes women, men and children to unacceptable risks from the earliest stages of life.

The inclusion of new substances

When the scope of the legislation is reviewed there will be an opportunity to adapt the legislation to include new hazards such as manufactured nanomaterials, which exhibit different properties from their larger counterparts and are currently being used in more than 500 consumer products³⁰. This would prove an essential application of the precautionary principle given their potential for adverse effects on human health and the environment.

Extending producer responsibility

NGOs need to make the case once more for a Chemical Safety Report to be required for ALL substances covered by REACH, regardless of their tonnage. This clear producer liability is also important to progressive companies, downstream users and trades unions, who should be encouraged to join the call for this basic reform. The collection of real-life cost data will be crucial, as industry has exaggerated costs throughout the legislative process and is likely to continue to do so.



30 | See <http://www.nanotechproject.org/index.php?id=44&action=intro>

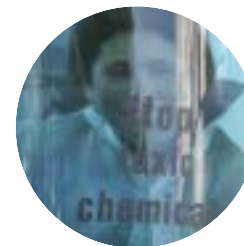
4.2 USE IT, DON'T LOSE IT!

As well as working to improve the REACH regulation, there are also opportunities for citizens and NGOs to use its provisions, including:

- Requesting information about the presence of “substances of very high concern” in consumer articles and putting pressure on companies to stop using them by substituting them with safer alternatives.
- Raising the awareness of the public about substances that are not being covered by REACH.
- Providing information to national governments and convincing them to request that specific chemicals should be evaluated, considered for authorisation or for restriction.
- Requesting proper enforcement including inspections of chemical companies and of down-stream user facilities.
- Either request or conduct their own monitoring-schemes to measure levels of hazardous substances in both humans and the environment, to check whether REACH is delivering any measurable improvement and identify if there is a need for further action.

REACH also creates opportunities for organisations outside Europe to promote improvements in their own national legislation on chemicals, in particular by using the publicly-accessible database of chemical hazards and properties to be generated under REACH. Non-EU NGOs could also expose double standards, where companies avoid the use of hazardous substances for export to the EU market but continue to use these substances elsewhere.

By using these opportunities that have been presented by REACH, NGOs and citizens can spur the transition to a society where hazardous chemicals are ultimately phased out completely.



27 June 2003 - HAMBURG, GERMANY. Greenpeace installs a giant test tube at the EU chemical industry's meeting venue in Hamburg. Inside the two meter-high model, a Greenpeace activist is standing up to her neck in a green liquid symbolizing hazardous chemicals.



toxics

On behalf of coalition, two children present European Commissioner Wallstrom with the "Declaration for a Toxics Free Future."



main image: © Anna Milkova
smaller images: © WWF | © Kameel4u

5.1 HISTORY OF REACH ADOPTION

- 25.04.1998 An informal meeting of EU Ministers in Chester, UK, submits a document outlining the current lack of action and the need for a completely new policy on chemicals
- JUNE 1999 EU Environment Ministers that met at the Environment Council request a strategy for chemicals reform from the European Commission
- 13.02.2001 European Commission, White Paper on the Strategy for a Future Chemicals Policy
- 07.06.2001 Council opinion on White Paper
- 15.11.2001 Adoption of European Parliament report on White Paper
- MAY 2003 European Commission Directorate General for Environment and Directorate General for Enterprise jointly publish a draft proposal concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)
- 16.06.2003 Beginning of 8 weeks public internet consultation on the full draft REACH text
- 29.10.2003 Commission publishes its proposal for a Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), and establishing a European Chemicals Agency
- 17.11.2005 The European Parliament votes its First Reading Opinion on REACH
- 13.12.2005 EU Member States in the Council of Ministers reach a political agreement for a common position on REACH
- 27.06.2006 EU Member States in the Council of Ministers formally approve a common position on REACH
- 13.12.2006 The European Parliament votes in second reading on REACH
- 18.12.2006 EU Member States in the Council of Ministers adopt the REACH regulation
- 01.06.2007 REACH enters into force



Commissioner Wallström addressing NGOs and press upon receipt of the 'Declaration for a Toxics Free Future'. Brussels, July 2003.

5.2 NGOS' PRIORITY DEMANDS ON REACH



FEBRUARY 2005

JOINT BRIEFING FOR THE 1ST READING
DISCUSSIONS IN THE EUROPEAN PARLIAMENT

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.



MARCH 2006

JOINT BRIEFING FOR THE 2ND READING
DISCUSSIONS IN THE EUROPEAN PARLIAMENT

Key priorities of Environmental, Health, Consumer and Women's NGOs

Will REACH be a wasted opportunity for making chemicals safe in the EU or will it be a first step towards the protection of human health and the environment from the most hazardous chemicals? This is the political choice European legislators have to make in the coming months. NGOs think that there is little left from the already weak original proposal and call for the following four points to be safeguarded in the REACH legislation to deliver a minimum level of protection to citizens and the environment.

1. **Play it safe: Replace hazardous chemicals with safer alternatives whenever they exist.**

The REACH system needs to systematically promote safer alternatives, which are suitable to replace chemicals which cause cancer, affect DNA, or the reproductive system or those that build up in our bodies and the environment or interfere with the hormone system. The continued use (Authorisation) of the most hazardous chemicals should:

- Only be granted if no safer alternatives are available and the use is essential to society (as proposed by the European Parliament).
- Be time-limited to a maximum of five years in order to foster innovation and the development of safer alternatives (as proposed by the European Parliament).
- take into account the analysis of alternatives and a concrete substitution plan to be submitted by the applicant as well as substitution information provided by third parties (as proposed by the European Parliament).

2. **Information improves trust: Provide sufficient safety information to identify dangerous chemicals and safer alternatives.**

Transparent safety and use (exposure) information via the Registration process is essential to enable companies and the authorities to take informed decisions on the safe management of chemicals and identify safer alternatives. Under REACH, companies should:

- Provide information on long-term effects, including reproductive toxicity, at higher tonnage bands (>10tpa) (as proposed by the Council).

- Provide good quality use and exposure information (scenarios) (as proposed by the Council)
- Define risk management measures as required in the Chemical Safety Report from 1 tpa onwards (as proposed by the European Parliament), otherwise the safety information will not result in any practical improvements.

3. **A legal guarantee: Ensure the chemical industry's responsibility for the safety of their products (Duty of Care).**

Chemical manufacturers, importers and users must be responsible for the safety of their products (as proposed by the European Parliament). They should guarantee that these products do not negatively affect human health or the environment. Clear legal provisions must apply for all chemicals, regardless of production volume, which would simply codify existing voluntary commitments by industry.

4. **Transparency for consumer products: Establish a right to know for citizens.**

Sufficient information to allow chemical users and consumers to make informed choices must be publicly available. Information must be handed down the supply chain to enable retailers and consumers to find out about hazardous chemicals in products.

- Citizens must have the right to ask about substances present in EU-made and imported products they buy; all articles which contain chemicals of very high concern need to be labelled (as proposed by the European Parliament).
- The list of non-confidential information in REACH needs to be extended to all information relevant for the environment and human health, in line with the Aarhus Convention.
- Industry should always be obliged to give transparent justifications when applying for information to be kept confidential.
- As a result chemical producers will carry little responsibility for the safety of their products.
- Many important decisions have been delegated to technical bodies or comitology procedure, which excludes democratic oversight by the European Parliament.
- The Chemicals Agency bureaucracy has been increased without an assessment of whether it will be able to properly fulfil its tasks.

Background: Five years ago civil society organisations called REACH a once-in-a-lifetime opportunity to reform Europe’s chemicals policy. Today, following huge concessions to industry, little of that opportunity remains:

- Basic health and safety information will not be provided for the majority of low volume chemicals (two thirds of the substances covered by REACH, or 17,500 substances).
- The same holds for higher volume chemicals, which may be registered without proper assessment of their toxicological effects, such as developmental and reproductive toxicity.

On the positive side, a consistent authorisation procedure now applies at least to bioaccumulative and persistent chemicals, which should reduce the use of such chemicals in everyday products and encourage innovation towards safer alternatives. However, this is too little progress for a law that will replace some 40 pieces of legislation, at a time when the health threats of chemicals are increasingly being uncovered. Therefore, we call on all decision-makers to improve the text in key areas and make sure REACH will protect humans and the environment.

NGOs’ 4 key demands:

- 1. Play it safe: Replace hazardous chemicals with safer alternatives whenever they exist.**
- 2. Information improves trust: Provide sufficient safety information to identify dangerous chemicals and safer alternatives.**
- 3. A legal guarantee: Ensure the chemical industry’s responsibility for the safety of their products (Duty of Care).**
- 4. Transparency for consumer products: Establish a right to know for citizens.**

5.3 REGISTRATION REQUIREMENTS ACCORDING TO VOLUME OF PRODUCTION OR IMPORT

	Registration deadline for phase in substances	Registration requirements (Article 12)
1000 tpa and above	30 Nov 2010	<ul style="list-style-type: none"> • Chemical Safety Report • Annex IX and X proposals for testing and Annexes VII and VIII
CMR 1tpa and above	30 Nov 2010	<ul style="list-style-type: none"> • Chemical Safety Report according to tonnage band
R50-53 100 tpa and above ³¹	30 Nov 2010	<ul style="list-style-type: none"> • Chemical Safety Report according to tonnage band
100-1000 tpa	31 May 2013	<ul style="list-style-type: none"> • Chemical Safety Report • Annexes VII and VIII • All other available and relevant information the registrant has • Annex IX proposals for testing for the purpose of the registration
10-100 tpa	31 May 2018	<ul style="list-style-type: none"> • Chemical Safety Report • Annexes VII and VIII • All other available and relevant information the registrant has
1-10 tpa	31 May 2018	<ul style="list-style-type: none"> • No Chemical Safety Report <p>Distinction between:</p> <ul style="list-style-type: none"> • substances meeting one or both criteria set out in Annex III: submit information of Annex VII and any other available information • other substances: set of physicochemical information and any available and relevant (eco)toxicological information

31 | Very toxic to aquatic organisms and may cause long term adverse effects in the aquatic environment.

5.4 SAMPLE LETTER FOR CONSUMERS TO REQUEST INFORMATION ABOUT SUBSTANCES IN ARTICLES

Date

Dear Sir/Madam

In accordance with the new European regulation on Chemicals, REACH, I am writing to ask you to inform me about the presence in the product XX or its packaging of any chemical from the group of "substances of very high concern" as specified by REACH.

Should any of these substances be present in the product XX or its packaging, I wish to be informed about the name of this substance, and receive sufficient information on how I can protect myself and the environment from it.

I would be grateful to receive this information within 45 days as required by REACH.

I would also be grateful if you would inform me about steps you are taking to provide products intended for the same use but which do not contain such potentially hazardous chemicals.

Yours faithfully,

SAMPLE LETTER FOR CONSUMER
TO REQUEST INFORMATION ABOUT
SUBSTANCES IN AN ARTICLE.



cc: European Chemicals Agency - P.O.Box 400,
00120 Helsinki, Finland, phone: +358-9-686180
email: info@echa.europa.eu, www.echa.europa.eu
(visiting address: Annankatu 18, 00120 Helsinki)
Your national consumer and/or environmental organisation

5.5 LIST OF COMPETENT AUTHORITIES

The following is a list of Competent Authorities in EU Member States; further details can be obtained from:

http://ec.europa.eu/echa/reach/helpdesk/nationalhelp_contact_en.html

Austria

Austrian Federal Ministry of Agriculture, Forestry, Environment and Water Management
Division V/2
Product-related environmental protection
Mr. Thomas Jakl
t: +43 151522-2330
f: +43 151522-7334

Belgium

Risk management Service of the Directorate General
Place Victor Horta 40, Box 10, B 1060 Bruxelles
Jeanine Ferreira Marquez
t: +32 (0) 2 5249588
f: +32 (0) 2 5429603
e: jeanine.ferreira@health.fgov.be

Bulgaria

Ministry of Environment and Water (MoEW)
Director of "Coordination of RIEWs"
Directorate MoEW
Ms Svetla Kraptcheva
t: +359 2 940 60 27
f: +359 2 980 3317; 981 3384
e: kraps@moew.government.bg

Chief Expert "Operative Control and Management of Dangerous Chemical Substances" Department, MoEW
Ms Parvoleta Luleva
t: +359 2 640 6021
f: +359 2 980 3317; 981 3384
e: pluleva@moew.government.bg

Cyprus

Department of Labour Inspection
www.mlsi.gov.cy
Maria Orphanou
t: +357 22405609
f: +357 22663788
e: morphanou@dli.mlsi.gov.cy

Czech Republic

Ministry of Environment
www.env.cz/
Mr Josef Hasa
t: +420 267122025
e: josef_hasa@env.cz

Denmark

Danish Environmental Protection Agency
<http://glwww.mst.dk/homepage/>
t: +45 72544000
f: +45 32660479
e: reachspm@mst.dk

Estonia

Chemicals Notification Centre
Gonsiori 29, ET-15027 Tallinn
Enda Veskimäe
67, William Gladstone Street, BG 1000 Sofia
t: +372 6269396
f: +372 6269395
e: enda.veskimae@sm.ee

Finland

Finnish Environment Institute (FEI)
www.environment.fi
t: +358 20490123
f: +358 204902190
e: kirjaamo.syke@ymparisto.fi

Working with the National Product Control Agency for Welfare and Health
www.sttv.fi
t: +358 32608200
f: +358 32608222
e: sttv@sttv.fi

France

*Ministère de l'Écologie, du Développement
et de l'Aménagement Durables*
www.ecologie.gouv.fr/-REACH-.html
e: ministere@ecologie.gouv.fr

Germany

*Federal Institute for Occupational
Safety and Health*
Division 5 – Chemicals,
Notification and Authorization
www.baua.de
t: +49 1803214321
e: reach-info@baua.bund.de

Greece

Ministry of Economy & Finance
General Secretariat of Taxation & Tarrification
Directorate General of General Chemical
State Laborator
Division of Environment
Ioanna Angelopoulou
t: +30 2106479407
f: +30 2106466917
e: elhelpdesk@ath.forthnet.gr

Hungary

National Institute of Chemical Safety
Nagyvarad ter 2, H-1096 Budapest
Krisztina Csengody MD
t: +36 1 476 1184
f: +36 1 476 1227
e: csengody.okbi@okk.antsz.hu

Ireland

Health and Safety Authority
www.reachright.ie
t: 1890 289 389
f: 01 614 7020
t (from overseas): +353 16147000
e: wcu@hsa.ie

Italy

Ministero della Salute
www.ministerosalute.it/
Dott.ssa Francesca Fratello
t: +39 0659943770
f: +39 0659943278
e: f.fratello@sanita.it

Dott.Salvatore Squarcione
t: +39 0659943687
f: +39 00659943554
e: s.squarcione@sanita.it

Dott.Pietro Pistolese
t: +39 059943439
f: +39 00659943554
e: p.pistolese@sanita.it

Latvia

Latvian Environment Agency,
Division of Chemicals Register
www.lva.gov.lv/chemical/eng/index.htm
t: +371 7755409
f: +371 7764162

Lithuania

Environmental Protection Agency
http://aaa.am.lt/VI/index.php
Lina Lukinskiene
Head of Risk Assessment Division,
Department of Chemical Substances
t: +370 52126092
f: +370 52662800
e: l.lukinskiene@aaa.am.lt

Luxembourg

Administration of Environment
www.emwelt.lu
M. Claude Geimer
t: +352 405656-1
f: +352 496256
e: infos@aev.etat.lu

Malta

Malta Standards Authority
www.msa.org.mt/
Tristan Camilleri
t: +356 21255546
e: tristan.camilleri@msa.org.mt

Netherlands

Bureau REACH
www.rivm.nl/br/
t: +31 30 2744077
f: +31 30 2744401
e (new chemicals): bms.ns@rivm.nl
e (existing chemicals): bms.bs@rivm.nl

Poland

*Bureau for Chemical Substances
and Preparation*
www.chemikalia.gov.pl/
t: +48 426314679
e: biuro@chemikalia.gov.pl

Portugal

Direcção-Geral das Actividades Económicas
e: isabel.laginha@dgempresa.min-economia.pt

Romania

36-38 Mendeleev st, flr 7, d 1, 010366 Bucharest
www.anspcp.ro
t: +40 21 316 79 94
f: +40 21 316 79 96
e: carina.darasteanu@anspcp.ro

Slovakia

Centre for Chemical Substances and Preparations
Mierova 19, SK - 827 15 Bratislava
Mr Peter Rusnak
t: +421 2 4854 4512
f: +421 2 4854 4555
e: rusnak@cchlp.sk

Ministry of Economy of the Slovak Republic
Mierova 19, SK - 827 15 Bratislava
Mr Jaroslav Soltys
t: +421 2 4854 1833
f: +421 2 4333 3595
e: soltys@economy.gov.sk

Slovenia

Ministry of Health National Chemicals Bureau
Mali trg 6, SI-1000 Ljubljana, Slovenia
www.mz.gov.si
Simona Fajfar
t: +386 14786053/6051
f: +386 14786266

Spain

Ministry of Health
Paseo del Prado 18-20, ES- 28071 Madrid
Fernando Carreras
t: +34 91 5962085
f: + 34 91 3601341
e: sgsasl@msc.es

Plaza de San Juan de la Cruz s/n, ES-28071 Madrid
Israel Pastor
t: +34 91 453 53 79
f: +34 91 534 05 82
e: buzon-sgcapr@mma.es

Sweden

Swedish Chemicals Inspectorate
www.kemi.se/
t: +46 851941100
e: kemi@kemi.se

UK

Health and Safety Executive
www.hse.gov.uk/reach/index.htm
t: +44 (0)8453450055
f: +44 (0)8454089566
e: hse.infoline@natbrit.com

Working with the UK's Environment Agency
www.environment-agency.gov.uk/
t: +44 (0)8708506506
e: enquiries@environment-agency.gov.uk

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WWF REACH Briefing, 08 Dec. 2006 http://www.panda.org/about_wwf/where_we_work/europe/what_we_do/epo/index.cfm?uNewsID=89301

WWF DetoX factsheet animal testing <http://assets.panda.org/downloads/detoxfactsheetanimaltesting.pdf>

WWF bloodtesting from testing 3 generation in European families http://www.panda.org/about_wwf/where_we_work/europe/what_we_do/epo/news/index.cfm?uNewsID=23635

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REACH - What Happened and Why? The Only Planet Guide to the Secrets of Chemicals Policy in the EU, April 2004 <http://assets.panda.org/downloads/theonlyplanetguide.pdf>

5.7 GLOSSARY³²

Adequate Control The concept of “adequate control” is based on the assumption that there is an acceptable level of risk, or a “safe threshold” below which adverse effects do not occur, and that regulators together with industry can determine acceptable levels of exposure from these risk calculations (see page 25). The current state of contamination of wildlife and people with hazardous chemicals show clearly that this approach is flawed for all substances of very high concern.

Annex XIV List of substances subject to authorisation.

Authorisation As required by REACH: the use and marketing of substances of very high concern will require an authorisation. In some cases this may mean an obligation to replace them with safer alternatives.

Authorisation dossier Dossier prepared by a company to support a specific use of a substance that requires authorisation. Amongst other information, it contains an analysis of alternatives.

Candidate list A list of substances of very high concern (SVHC), drawn up by the European Chemicals Agency that will eventually become subject to authorisation.

Comitology Comitology refers to the committee system which oversees the acts implemented by the European Commission. The committees, which are forums for discussion, are made up of representatives from EU Member States and are chaired by the Commission. They ensure that the Commission is able to establish a dialogue with national administrations before implementing measures.

The Commission Short for the European Commission.

Competent Authorities These are the government bodies responsible for enforcement of REACH within each EU Member State.

CSA This is a risk assessment, carried out by the producer of a substance, known as a ‘Chemical Safety Assessment’, (CSA) which is documented in the Chemical Safety Report. This is required for substances produced or imported in quantities over 10 tonnes per year.

CSR Chemical Safety Report, see also CSA.

CMR Carcinogens (cause cancer), mutagens (cause gene mutations), or toxic to reproduction (CMR category 1 and 2).

CRAP Community Rolling Action Plan: lists which substances have been targeted for the substance evaluation process.

Dossier (registration dossier) Registration requires manufacturers and importers to provide specific information on their substances and to use that data to manage them safely. There is a general obligation for manufacturers and importers of substances to submit a “registration dossier” to the Agency.

ECHA, also the Agency European Chemicals Agency, based in Helsinki, Finland.

EDCs Endocrine Disrupting Chemicals. These are chemicals which interfere with the hormonal systems of people and wildlife, in particular with the thyroid hormones and sex hormones.

EU European Union is a supranational and intergovernmental union of 27 Member States. Ministers from the Member States make up the “*Council of Ministers*”.

The European Parliament is the directly elected parliamentary body of the European Union with elected Members from each Member State; together with the Council, the Parliament forms the legislative branch of the EU.

The European Commission is the main law-making and executive body of the European Union; it consists of 27 Commissioners from each of the Member States and is supported by an administrative body, divided into departments called “Directorate-General”.

The Court of Justice of the European Communities usually called the European Court of Justice, is the highest court of the European Union. It is based in Luxembourg City, unlike most of the rest of the European Union institutions, which are based in Brussels and Strasbourg.

Evaluation As required by REACH: evaluation of the registered (and other) information by the European Chemicals Agency and Member State authorities to determine hazards and risks.

GLP Good Laboratory Practice.

Health and Safety Data ‘Health’ refers to the toxicological and ecotoxicological data that tell us about how a substance behaves in the environment and in living organisms - the ways in which it may be poisonous. ‘Safety’ refers to the physical/chemical properties of a substance, such as whether it is explosive, corrosive, its boiling point, evaporation point, etc.

NGOs Non-governmental organisations, such as health, environmental, women’s and consumer groups.

OSPAR OSPAR Commission for the Protection of the Marine Environment of the Northeast Atlantic: <http://www.ospar.org>. The Contracting Parties to the Oslo and Paris Conventions are Belgium, Denmark, the European Union, Finland, France, Germany, Iceland, Ireland, the Netherlands, Norway, Portugal, Spain, Sweden, and the UK. In July 1998 (Sintra Statement) OSPAR identified a List of Chemicals for Priority Action, which were targeted for the “cessation of discharges, emissions and losses ... by the year 2020”.

PBT Persistent, Bioaccumulative and Toxic substances: Persistent - degrade slowly or do not break down at all, Bio-accumulative - accumulate in human bodies and the environment.

vPvB very Persistent and very Bioaccumulative (see PBT above).

phase-in substances Substances produced or marketed before 1981.

PPORD product and process orientated research and development.

Precautionary Principle The obligation to take preventive action when a chemical is suspected of causing harm to human health and/or the environment in the absence of conclusive scientific evidence in order to ensure a high level of environmental protection and of human, animal and plant health.

REACH abbreviation for the new EU Chemicals legislation – “Registration, Evaluation, Authorisation and restriction of CHemicals”.

Registration As required by REACH: registration of basic health and safety information of substances produced in or imported to the EU over 1 tonne per year per producer or importer, to be submitted by companies.

Restriction As required by REACH; restriction of the uses of chemicals with properties of concern at Community level.

Safe Threshold A level below which adverse effects do not occur, also see “Adequate Control” above.

SEA Socio-economic Analysis.

Substitution Principle The Principle of Substitution states that hazardous chemicals should be systematically replaced with safer available alternatives. These alternatives could be either chemical, material or functional (technological).

CONTACTS

SVHC Stands for “Substances of Very High Concern”, which are required to be authorised under REACH. These are substances which fall into one of these classifications/categories:

- carcinogens (cause cancer), mutagens (cause gene mutations), or toxic to reproduction (CMR category 1 and 2),
- Persistent (degrade slowly or do not break down at all), Bio-accumulative (accumulate in human bodies and the environment) and Toxic (PBT),
- very Persistent and very Bio-accumulative (vPvB), or
- identified from scientific evidence as causing probable serious effects to humans or the environment equivalent to those above on a case by case basis, for instance substances that interfere with the hormone system.

Third (interested) parties These include any private or public organisation (e.g. individuals, public authorities, NGOs, international organisations and non-EU countries). Third parties do not have obligations under REACH but they may provide information on substances to the Agency.

tpa Tonnes per annum.

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Sixteen top fashion designers participate in 'Moda sin Tóxicos', a catwalk show organised by Greenpeace, to phase out chemicals currently widely used in clothing, which can harm the immune and nervous system, affect genital development, cause reproductive disorders and cancer. © Jean-Marc Manson/Greenpeace.

FOR MORE INFORMATION, SEE 'MY VOICE: HOW YOU CAN DEMAND BETTER PROTECTION OF HUMAN HEALTH AND THE ENVIRONMENT FROM HAZARDOUS CHEMICALS,' WWW.CHEMICALREACTION.ORG

CHEMICAL REACTION

Chemical Reaction is a joint project of the EEB, FoEE and Greenpeace

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