Chemicals
UNDER THE SPOTLIGHT
-FROM AWARENESS TO ACTION
Chemicals under the spotlight

From awareness to action

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Today there is enough for the consumer to worry about when it comes to chemicals in our everyday life and the environment since the consequences are very difficult to foresee.

In Europe we managed to stop the use of certain chemicals like DDT, which was shown to be very hazardous. Nevertheless dangerous chemicals are still out there, since they do not easily degrade in nature. Further, we must face the fact that the mix of chemicals, the so-called cocktail effect, has never been taken into account in EU legislation. On top of this there has been a significant increase in the number of danger signals and disturbing examples.

- A matter of increasing concern is that the extremely dangerous environmental poison dioxin, given off during incineration, is found in women’s breast milk. Could this be linked to the increase in breast cancer?

- Moreover, some scientific research shows that our reproductive ability is being threatened by a declining semen quality and an increasing number of cases of testicular cancer. Is this linked to the chemicals around us?

The latest research results on endocrine disrupters, which are found in a large number of common consumer products, are worrying. They are, for example, found in cosmetics, paints, detergents and cleaning agents. When we sit in front of the television or the computer, or when the children play with their teddy bear, we are exposed to endocrine disrupters, the long-term effects of which are subject to much uncertainty. Research has also shown that fish, which have been exposed to pesticides and other endocrine substances, lose their sexual urge. Further, male fish, which have been exposed to polluted wastewater, will develop female sexual organs and roe in their testicles. Endocrine disrupters are spread everywhere in the environment, and changes in sexual organs have even been found among polar bears.

It is time that the EU tackles legislation on chemicals in a far more consistent way. European consumer and environmental organisations have united in launching the campaign "Chemical Awareness". With this policy discussion paper we would like to draw your attention to the future EU policy on chemicals.

It is our hope that many of you will commit yourselves to ensuring good health and a clean environment for future generations of Europeans.
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The global consumption of industrially produced chemicals has skyrocketed in recent decades.
A large number of industrial chemicals are known to cause harm to our environment and our health.
Substances that cause cancer or reproductive disorders, endocrine disrupters, allergens and numerous other hazardous chemicals are widespread in consumer products, air, soil, water, food, and living organisms.

Currently the EU is in the process of developing a new strategy on chemicals, since the current legislation is marred by a large number of serious backlogs and inadequacies. The current chemicals policy fails to address several core principles enshrined in EU policy, as set out in the Treaty. The precautionary principle is not adequately reflected. The chemicals policy does not contribute towards enabling Member States to meet international conventions, and finally, there is a widespread violation of the right to information and participation in the EU chemicals policy as we see it today.
As a result there are worrying signs of increasing risks to people and their environment.

The administration of industrial chemicals is characterised by two serious backlogs:

- Lack of information
  - There are no obligations on producers and importers to provide the sufficient data needed to classify chemicals according to their overall effects on environment or human health. Moreover, the required self-classification can be done without any documentation or control.

- Lack of regulation
  - There are far too many hazardous chemicals on the market, which should have been banned years ago. Too much time and too many resources have been wasted on assessing chemicals, and no action has been taken.

The overall objectives of the new chemicals strategy in the EU must be to phase out substances with unacceptable effects on the environment and human health and to reduce the total amount of non-assessed chemicals on the market. In order for the new strategy to be successful it must include several substantial procedural changes. This paper presents a number of proposals for the revision of current practises. It also highlights three fundamental principles on which any revision of the current policy should be based. Our proposals are summarised below:
**Build new policy on three guiding principles**

- The precautionary principle, which implies that hazardous substances are kept away from the environment and the consumers.
- The principle of substitution, which encourages the substitution of hazardous chemicals with safer alternatives.
- Democratic principles, which ensures public access to information and balances industry’s involvement in the decision making process with that of other stakeholders.

**New approaches to hazard assessment and classification procedures**

- Set up a deadline - in 2005 - by which all non-assessed chemicals are removed from the market.
- Speed up classification by using group classification and predicted data in cases where no experimental data exist.
- Ensure independent reviews of the self-classifications performed by the producers.

**Speed up or leave out the risk assessment procedure**

- Market restrictions for substances with severe hazardous properties must be based on hazard evaluations rather than full-scale risk assessments.
- Set up clear deadlines for the completion of risk assessment reports and implementation of risk management strategies.

**Tighten up on the regulation of harmful chemicals**

- Phase out chemicals that affect our environment or our health.
- Expand the current approval scheme approach for pesticides, biocides, food additives and pharmaceuticals to include more product groups in order to reverse the “burden of proof”. Producers should prove that their products are safe rather than victims or public authorities having to prove danger.
- Ensure public access to information on what chemicals are used in which products and balance stakeholders’ influence on chemicals policy.
- Introduce additional regulation measures such as green taxes, green public procurement and eco-labelling, within the framework of an Integrated Product Policy.
Throughout the 20th century human and environmental exposure to hazardous chemicals has gradually intensified. Tens of thousands of industrial chemicals are being marketed and used in the European Union every day. Many of these chemicals are released without restrictions and with no knowledge of their properties. We use industrial chemicals for solving problems, though we do not know the consequences or the price to be paid, in the form of environmental degradation and poor public health. The use of chemicals creates a central conflict in our modern technological society. The conflict lies between our desire for convenient solutions to problems and the profits that often come with them – and the damage that such solutions may cause.

In a critical report from November 1998, the EU Commission concluded that the EU legislation on chemicals is outdated. The legal framework is unable to adequately cope with the increasing problems caused by hazardous chemicals. This led the Environment Council to call for a substantial revision of the current policy, and the Commission has announced that it intends to present the first document outlining a new chemicals strategy in the summer of 2000.

The regulation of chemicals within EU is highly harmonised. The bulk of national chemicals legislation is subordinate to EU legislation. This means that a revision of EU legislation will have profound impact on every citizen in the community.

This paper will give a brief overview of the current situation and also present a number of proposals for a new chemicals strategy. Obviously, these proposals do not amount to a final strategy. Many more subjects must be addressed and discussed before a full strategy is in place. However, it is the authors’ intention and hope that the paper will prove an inspiration for policy-makers in formulating the new chemicals strategy. We also hope that it may provide a basis for public debate and inspire readers to think about their own wishes for the future chemicals policy of the EU. It is of paramount importance that not only the chemical industry and the European Commission, but also environmental and consumer organisations, workers unions and concerned citizens are aware of the ongoing review process. All stakeholders should use this special opportunity to offer their own suggestions and visions for the future chemicals policy.
Update on recent history

Important steps leading to revision of the EU chemicals policy

• March 1998:
  Minutes released from informal discussions between Austria, the Netherlands, Finland, Denmark and Sweden on the EU chemicals policy.

• April 1998:
  The informal meeting of environment ministers in Chester acknowledges the March paper.

• September 1998:
  The European Environment Agency and UNEP publish a report, which draws attention to the problems with the current policy on chemicals.

• November 1998:
  The Commission publishes a critical working document on the operation of four major legal instruments in the EU chemicals policy.

• February 1999:
  The European Commission holds a stakeholder Brainstorming workshop in Brussels, entitled "Industrial Chemicals: Burden of the past – challenge of the future".

• June 1999:
  The Environment Council takes a positive step towards a fundamental review of the EU chemicals policy by giving a clear mandate to the Commission.

• Summer 2000 ?? :
  First proposal for new chemicals strategy by the Commission.
The global consumption of industrially produced chemicals has skyrocketed over the past decades. In 1930 the production of organic chemicals was approximately 1 million tons a year. Today it is about 400 million tons a year (EEA and UNEP, 1998).

Europe is the largest producer of chemicals worldwide, accounting for about one third of the world’s production. On a global scale chemicals production was an important part of the rapid economic development that took place in the ‘60s and ‘70s. Thousands of new materials and products were invented and placed on the market without much testing of the potential harmful effects of all those new chemical substances.

Today, it is clear that a large number of synthetic chemicals are known or suspected to be harmful to our environment and our health. These chemicals are found in numerous everyday products, such as detergents, paints and varnishes, furniture, carpets, toys, clothes, textiles, cosmetics, medicine, pesticides, building materials, computers, televisions, food and food packaging etc. Harmful substances can be released both during production, use and disposal of these products. The result is that manmade chemicals are becoming ever-present in the environment - in air, water, food, soil, sediments and living organisms.

Nonetheless, increasing amounts of hazardous chemicals are being produced and released each year. Figure 1 shows that the hazardous chemicals’ share of GDP has been rising in the period of 1990-1997.

Figure 1: European production and import of “dangerous chemicals / chemicals of concern”, compared to total chemicals production and GDP (EEA, 1999a).

This is a preliminary indicator based on the inadequate production data that industry and governments are obliged to submit to the European Chemicals Bureau. However, it is the most relevant available indicator of potential hazards to workers, consumers and the environment.
Unknown numbers

The exact number of chemicals on the European market is unknown. In 1981 a chemicals register was established (The EINECS list, European Inventory of Existing Commercial Chemical Substances). The register listed 100,106 chemical substances, but no one knows how many of these are being produced and marketed today.

The OECD has estimated that globally there were some 70 – 80,000 substances on the market in 1986. On the basis of data provided by the chemicals industry, the European Commission has estimated that in Europe about 20,000 substances are marketed in volumes of more than 10 tons a year. Of these, about 2,500 are so-called High Production Volume (HPV) chemicals, marketed in volumes of more than 1,000 tons a year. The remaining 80,000 chemicals from the EINECS list are either not produced or produced in volumes of less than 10 tons a year (EU-Commission, 1998).

Chemicals are generally marketed as mixtures. 90 - 95% of the chemicals found on the market are sold as ingredients in mixtures or preparations. The Commission estimates that there are about 1 million chemical preparations on the European market.

In addition, a vast number of by-products and impurities are never registered. These include intermediates or residuals from processing, chemicals from non-marketed semi-manufactured articles and a large number of degradation products.

Abysmal ignorance

The effects of the man-made chemicals that surround us in our daily lives, are by and large unknown. Most chemicals have never been assessed in terms of their harmful effects on health and environment (see later). It has been estimated that for more than 85% of the 2,500 HPV chemicals little or nothing is known (Allanou et al., 1999) and it is likely that the situation for chemicals produced in lower volumes is worse.

Only some 2,600 chemicals or groups of chemicals (about 4,800 single substances) have been officially classified as dangerous in accordance with the safety regulations of the EU. Of these, about 2,000 have been assessed according to their environmental impacts.

In addition, the producers have classified approximately 4,000 substances themselves; however there is no external quality control of these self-classifications.
Limited data requirements

The data requirements for chemicals differ, depending on whether they were already on the market before 1981 (Existing Substances) or were introduced after 1981 (New Substances). For those chemicals that were on the market before 1981, i.e. the 100,106 chemicals on the EINECS list, data requirements are very few.

For “new substances” the producers and importers are obliged to provide some basic data (notification) before they can place a substance on the market. These chemicals are registered in the European List of Notified Chemical Substances (ELINCS), which presently contains about 2,400 chemicals. However, these new substances are mainly produced in small volumes of 100 tons or less, and the share of new substances on the market is no more than 1% of the total volume of chemicals.

Figure 2:
The number of classified chemicals and chemicals chosen for risk assessment compared to the total number of chemicals on the EINECS- and ELINCS lists

- Total number of chemicals on the EINECS and ELINCS lists (103,000)
- Chemicals classified by the producers (4,000)
- Officially classified (2,600)
- Selected for risk assessment (110)
- Risk management strategy completed (3)
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Köp inte onödiga antibakteriella produkter

..rischi associati all'esposizione a MTBE...

PVC IM BLUT

Ympäristömyrkyt

Chemicals allergies.

Doctors speak out!

Peintures toxiques:
Une décontamination qui progresse à pas d'escargot...Depuis les années 60, une substance appelée tributyl-étain (TBT) est employée...
Adverse effects of industrial chemicals

- A few examples.

Industrial chemicals that cause poor health and environmental problems can be characterised by their Persistence, Toxicity, and ability to Bioaccumulate.

The acronym "PTB" is often used for chemicals with these unpleasant characteristics. On these pages we take a closer look at some of their effects by focusing on just a few sub-groups of the vast chemicals universe.

Some chemicals belong to more than one of the groups shown here. The four examples are selected based on overlapping criteria of toxic effects (endocrine disruption, allergy) and systematic relationships (organic halogens and heavy metals).

### Endocrine disrupters

Affect the reproductive health of humans and wildlife

Synthetic chemicals that can act as endocrine disrupters are produced for many different purposes. Even in very small concentrations endocrine-disrupting chemicals may interfere with the normal endocrine functions and balances of living organisms causing serious malfunctions in the organism itself or its progeny.

This is a particularly serious threat, since many endocrine disrupters are persistent and bioaccumulating. In humans, endocrine disrupters are suspected to cause testicular cancer, breast cancer, reduced sperm count and malformation of male genital organs.

In animals, endocrine disrupters cause changes in the female sexual organs, e.g. "imposex" in sea snails. In fish the substances cause hermaphroditism, formation of female egg yolk protein in male fish, and reduced fertility.

There are also indications that endocrine disrupters may cause behavioural disturbances in both humans and animals.

### Organic halogens

Numerous toxic effects and omnipresent in environment and human bodies

Organic halogens combine carbon with one or more of the halogen-group elements, normally chlorine, bromine or fluorine. Large volumes of these substances are used in many products all over Europe. Generally, they tend to be persistent, to accumulate in the environment and to be toxic to humans and to other organisms as well.
Most of the 12 chemicals included in the global POPs convention are organic halogens. Many organic halogens form dioxin when burned. A number of organic halogens are ozone layer depleting and intensify the greenhouse effect. Some are suspected of being endocrine disrupters and several cause cancer.

Organic solvents are used in large quantities and they are among the most well-known groundwater pollutants. Among the biocides and pesticides, there are still many organic halogens and although well-known organic halogens such as DDT and PCB were banned several years ago they are so persistent that they are still omnipresent in the environment and in human bodies.

**Allergenic chemicals**

The key to a growing problem?

Asthma and allergies are becoming more and more widespread. There are several causes for allergies such as indoor environment, pets, dust and building materials.

Micro particles from diesel exhaustion are major culprits, but also fragrances, nickel, chromium, formaldehyde and phthalates in e.g. PVC floors can trigger allergies.

Some chemicals cause the victim to become an asthmatic, or susceptible to allergens, others provoke asthma attacks or allergic responses. Contact allergy is an irreversible illness and the only way to prevent it is to limit exposure to allergenic chemicals.

**Heavy metals:**

Old and well-known pollutants

Heavy metals are widespread in food and household products. Concentrations of heavy metals in soil are relatively high in many urban and industrial areas, and slightly elevated concentrations are widespread in the environment. At high concentrations, heavy metals have serious effects on physical or mental health, and they also have toxic effects at very low concentrations.

There are large temporal and spatial variations in the human ingestion of heavy metals, and at any point in our lifetime we are affected by our total consumption of heavy metals so far.

Nriagu (1988) has suggested that on a global scale over 1 billion (109) human beings are currently exposed to elevated environmental concentrations of toxic metals and metalloids, and several million people may be suffering from sub-clinical metal poisoning. This is also true for many animals in nature, particularly fish.
The EU chemicals policy is not integrated with environment and consumer policies

The chemicals policy was set up in the early days of environmental debate, before the potential hazards and the dramatic increase in production volumes were evident, and until this day environment and consumer protection policies have not been properly integrated into the chemicals policy or vice versa. For example, policies protecting marine and freshwater resources, and policies on waste prevention and waste recycling or efforts to control emissions do not take into account the possibilities of preventing pollution at source by regulating the production and use of chemicals.

The current chemicals legislation consists of a complex regulatory system with many interacting directives. However, four central legal acts may be seen as the core of the chemicals policy, and these will probably be the focus of the revision. They are characterised by being highly harmonised and by having the development of the Single Market as a primary objective. In this Chapter we will focus on some of the obvious inadequacies of these four legal acts.

Four legal acts representing the core of the EU chemicals policy

- Directive 67/548/EEC
  On the approximation of laws, regulations and administrative provisions relating to the classification and labelling of dangerous substances

- Directive 88/379/EEC
  On the approximation of laws, regulations and administrative provisions relating to the classification and labelling of dangerous preparations

- Directive 76/769/EEC
  On the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations

- Regulation (EEC) 793/93
  On the evaluation and control of the risks of existing substances

See Annex 1 for more information
Classification and labelling of dangerous substances and preparations

Directives 67/548/EEC and 88/379/EEC

The classification of chemical substances and compounds is of crucial importance since it forms the basis of later regulation against dangerous chemicals. The classification and labelling Directive was adopted in 1967 to approximate national provisions. However, the importance of protecting human health, in particular the health of workers handling dangerous substances, was also recognised. Protection of the environment was not included until much later - in 1979 with the sixth amendment - and even today, only few chemicals are classified with respect to their environmental effects.

The most substantial problem with this directive is the enormous lack of data on chemicals (Chapter 3). Today, chemical substances are generally tested and classified one by one. This is an extremely slow process, and if the number of chemicals on the market is compared with the resources available for performing experimental tests, it is easily concluded that the authorities will always be hopelessly behind.

If a new approach is not adopted, there will continue to be an enormous number of non-assessed substances on the market for many decades to come. There is no obligation on the producers and importers of “existing substances” (i.e. substances already on the market before 1981, which is about 99% of all substances) to generate new data, if available data do not allow a judgement as to whether or not a substance should be classified dangerous.

Test capacity overload

One reason why progress made in regulation is so slow compared to the extent of the problems, is the general demand for “certainty” of a direct correlation between substance and harm.

This demand is particularly unreasonable because it is impossible - on a global scale - to increase the testing capacity for hazardous chemicals, if they have to be tested one by one.

Review on chemicals.
The Danish Ministry of Environment and Energy, 1997
Dangerous substances not listed in Annex 1 to Directive 67/548 are classified and labelled by the importer or producer under his/her own responsibility. Seen from an environmental or consumer viewpoint, this self-classification scheme is not satisfactory. Producers and importers have classified about 4,000 chemicals on their own without independent quality control. In some cases the result has been different labelling of identical substances in different Member States. Manufacturers may evaluate the available information differently, and the authorities have little possibility of controlling what information the final labelling is based on. For example, DINP (Di-Iso-Nonyl Phthalate), a chemical substance used for softening PVC plastic, is labelled as carcinogenic for laboratory uses in the UK, while in Denmark it is being sold for laboratory use without any such labelling (Greenpeace, 1997).

Most chemical substances are marketed as compounds of chemical preparations, and there is a very close link between the “Dangerous substances directive” and the “Dangerous preparations directive”. However, provisions regarding the classification and labelling of preparations or products are even milder than those applying to single substances. There are no notification requirements before placing a new preparation on the market, and until recently (new preparation directive, May 1999) there was no obligation to classify and label preparations according to their effects on the environment.

### Evaluation and control of the risks of existing substances

**Regulation (EEC) 793/93**

The aim of regulation 793/93 is to provide a structure for evaluating the risks posed by "existing" industrial chemicals. Unfortunately, the risk assessment work is marked by slow progress, lack of resources and commitment in Member States and heavy lobbying on part of the industry (EU Commission, 1998).

When this regulation was adopted in 1993, estimates were that 25 risk assessments could be completed each year. However, only a total of merely 35 risk assessment reports have been completed in the last six years, and by the end of 1999 only three risk management strategies had been adopted. None had been implemented.

Risk assessments (RAs) are performed by working groups with representatives from Member States, NGOs and industries. Formal RAs include quantification of production volume and evaluation of the hazardous properties of a given substance as well as evaluations of human (consumers and working environment) and environmental exposure to the substance. Risk assessments form the basis of EU decision-making on chemicals. The main argument for this is that such assessments shall provide a "full scientific disclosure".
Shortcomings of current legislation

This means not only establishing the substances' potentials for causing harm and/or adverse effects, but also stating the probabilities - i.e. risks - that such harm or effects will in fact occur. In reality, however, the risk assessments do not give the full picture. A number of issues are not taken into account by current RAs. Among these are:

- The combined effect of exposure to several chemical substances,
- The cumulative effects of continuing emission of persistent and bioaccumulating chemicals,
- Different behaviour of chemicals in different environments, e.g. slow degradation in a colder climate,
- Some delayed effects of exposure to chemicals as e.g. endocrine disrupters,
- Risk from disposal and recycling,
- Specific problems in local areas,

It is also notable that predicted or measured occurrences of hazardous chemicals in the environment are not always enough to trigger risk reduction measures. Not even if they are found in the open oceans or other remote areas or in higher levels of the food chain.

In the current RAs the prevailing orthodoxy is that as long as the actual or predicted concentration in the environment is less than the "Predicted No-Effect Concentration", there is no cause for alarm and no risk reduction measures are initiated. A more precautionary approach would use practical levels of 'negligible risk' as points of departure. These could be defined as concentrations in the environment at least 100 or 1,000 times lower than the No-Effect Concentration (Leeuwen and Hermens, 1995).

In addition to the inadequate perception of risk embodied in the current risk assessment procedure, there is yet another major problem. Chemicals consuming industries are not obliged to report which chemicals they use, and it has proved exceedingly difficult to track the downstream users of chemicals and thereby to establish when, where and how humans and the environment are likely to be exposed. Obviously it is not easy - in fact impossible - to conduct risk assessments without these data.

Considering the lack of data on hazards and use patterns and the substantial limitations in the identification and quantification of exposure pathways, the question is whether the current risk assessment approach provides adequate protection of the consumers and the environment?
Commission Communication on the precautionary principle

A step forward or backwards?

Potentially, the principle of precautionary action is a monumental shift of paradigm in environmental decision-making. It is essentially a legal response to scientific uncertainties. The principle was introduced into the EU Treaty in 1992, though not defined here.

In February 2000 the EU Commission released a long-awaited Communication on the precautionary principle (PP). The Communication is an "input to the ongoing debate" and aims to provide a common understanding and guidelines for the use of the PP in decision making. It is not "the final word", which is good news as there was no consultation with the NGOs over its content. This is contrary to one of its main recommendations for better risk assessment and decision making i.e. that the "procedure should be transparent and involve all interested parties as early as possible".

The Communication puts the slow and flawed risk assessment procedure at the centre of its approach, without acknowledging the need to greatly improve the methods of weighing up overall costs and benefits, and it:

- Recommends that interested parties should be involved only at the later risk management stage, after the scientific evaluation (or risk assessment) has been completed;
- Accepts the linear process of risk assessment by scientists being followed by risk management by others, without acknowledging that the alternative options analysis is part of the initial risk assessment stage, which should therefore involve NGOs etc;
- Assumes that more research, or more comprehensive risk assessments will reduce uncertainties, when in fact they may increase uncertainty as we come to recognise that we know less than we thought;
- Recommends "coherence" with other situations without acknowledging the difficulties of comparing situations under uncertainties, or of the possibility of previous decisions being not cautious enough;
- Limits the idea of restrictive actions to being "proportional" to levels of protection rather than to overall benefits, including questions of need and alternative options.

At the same time however, the Communication recognises that:

- The PP is applicable where "preliminary scientific evaluation" indicates that there are "reasonable grounds for concern" that "potentially damaging effects" may be inconsistent with the chosen level of protection, and where scientific evaluation cannot determine risks with sufficient certainty;
- "Acceptable risks" are political not scientific decisions;
- The absence of scientific proof, or of quantifiable exposures or dose/response relationships should not be used to justify inaction by the authorities, and
- Due account should be taken of advice from even a minority in the scientific community, if it is credible;
- The "burden of proof" may be shifted from the regulatory authorities to the producer on a case by case basis;
- The protection of health should take precedence over economic considerations, as noted by the European Court;
- Cost benefit analysis of action or lack of action over activities goes beyond an economic analysis to include overall long term effects and non-economic issues such as alternative options and their acceptability to the public;
- A total ban may, or may not, be the sole possible response to a potential risk;
- The measures based on the PP should be maintained as long as scientific information is "incomplete" or "inconclusive", and the risk still considered too high.

Uncertainty is not an excuse for in-action

The current EU chemicals policy is characterised by the reliance of politicians on - often unattainable - scientific certainty. The responsibility for a sound chemicals policy rests with politicians, and consequently it is necessary that politicians make use of the precautionary principle as a decision-making tool. Politicians should have a bias towards protecting public health and the environment - not just until the next election period but for future generations.
Should we rephrase our questions to the scientific community?

Traditionally, decision-makers’ requests for information from the scientific community have been phrased as follows: Can you present a scientific proof showing that the use of this substance will cause harm to people or environment?

We might ask a different question: What potential risks of using this substance can be predicted on the basis of the current scientific knowledge?

The answer to the second question would be quite different than the answer to the first - although not less “scientific” as the chemicals industry often claims.

The precautionary principle in feeble action
- Phthalates in PVC toys

Phthalates are primarily used in PVC plastic to make the material soft and pliable. Several of the most used phthalates are suspected endocrine disrupters. In December 1999, The EU agreed on a ban on six phthalate softeners in PVC toys, though only in products “intended to be chewed or sucked by children under three years of age”. This is a very limited ban inasmuch as small children will chew on everything - be it the producer’s intention or not. Small children also chew on the toys of their elder brothers and sisters. However, this ban may still be seen as an example of the precautionary principle put into practice.

Regulators call for precautionary action
Brominated Flame Retardants

Brominated flame retardants are used as fire restraining chemicals in computers, televisions and many other products. They are persistent, toxic and bioaccumulating. Concentrations are increasing in fish, dairy products, office environments and human breast milk. In December 1999, Sweden and Denmark reacted to this fact in a common memorandum to the Environment Council, which read:

"Measures concerning brominated flame retardants should be based on the precautionary principle… The state-of-the-art science does not allow the conclusion that releases of these substances into the environment will not cause harm in the future. Therefore, these groups of substances should be phased out as soon as possible."

The Council took note of the request.

Operationalisation of the precautionary principle
The Generation Target

The generation target was agreed upon at the 4th North Sea Conference of Ministers, 1995:

"The Ministers agree that the objective is to ensure a sustainable, sound and healthy North Sea ecosystem. The guiding principle for achieving this objective is the precautionary principle. This implies the prevention of pollution of the North Sea by continuously reducing discharges, emissions and losses of hazardous substances thereby moving towards the target of their cessation within one generation (25 years) with the ultimate aim of concentrations in the environment near background values for naturally occurring substances and close to zero concentrations for man-made synthetic substances."

This may be seen as “true precaution” since there are no requirements to prove on a substance-by-substance basis, that certain effects to man or environment have occurred or are likely to occur.
Restrictions on marketing and use

Directive 76/769/EEC

Substances restricted under Directive 76/769 are generally restricted for particular uses only. To date the directive has been amended 18 times providing restrictions to 42 groups of substances, covering about 900 individual substances most of which are cancer-causing substances banned for consumer use.

In the early days of the directive the general perception of risk focused on health hazards rather than environmental risks. Restrictions on substances endangering the environment were not introduced until the early 1990s. This is still obvious in the directive, as provisions aiming at protecting the environment are far less frequent than provisions on substances presenting health hazards.

There is a serious “regulation back-log” in the EU. We fear there are far too many hazardous chemicals on the market that should have been subject to regulation years ago. The most obvious malfunction of the current policy is that the “burden of proof” lies with the environment and health authorities, not with the producers and importers of harmful substances. In this respect it is an obvious mistake that responsibility for assessing the need for risk management, in the form of marketing and use restrictions, lies with DG Enterprise and not with DG Environment or DG Health and Consumer protection. There is a traditional conflict between environment/consumer protection and free trade, and DG Enterprise’s main concern is to protect the competitiveness of the chemicals industries.

In recent years, efforts to limit the use and marketing of chemical substances have practically come to a full stop. This is partly due to lack of consensus between Member States as to what substances should be regulated, and partly due to the problems described in the previous sections. The slow progress of the RA procedures has detrimental effects on the practical regulation of chemicals, because some Member States insist that nothing can be decided until the full RA-procedure has been completed.

Considering the limited knowledge on chemicals combined with the potential seriously harmful effects (e.g. cancer, allergy, endocrine disruption, decline in fertility) the question is if the logical consequence would not be to intensify regulations on the marketing of chemicals - as opposed to the current policy where the less available information on a chemical substance, the less regulation is enforced.
General failures of the current policy

The current EU policy on chemicals fails to address a number of important principles, some of which are enshrined in the EU environmental policy as set out in the Treaty.

**Failure to apply the precautionary principle.**
The precautionary principle is mentioned in the EU Treaty (Article 174) as a guiding principle in the making of EU environmental legislation. The principle is, however, not defined in the Treaty and has not been translated into operative goals. In EU chemicals policy, the precautionary principle is certainly not the dominant aspect. The burden of proof is generally on the regulators, and there are no general policies against many of the most hazardous chemicals.

**Failure to uphold the public right to information and participation**
Today, the general public in the EU is unable to make informed choices about what chemical substances we wish to buy, since there is limited access to information on which hazardous chemicals are found in which products. In addition, the chemicals industry has an extensive and unjustifiable influence on EU chemicals policy compared to other stakeholders. Due to lack of resources consumer and environmental organisations are not able to participate in the decision-making processes on equal terms with the industry.

**Failure to establish sound divisions of responsibilities**
The current policy lacks a clear division of responsibilities between the chemicals industry and the environment and health authorities. No one is responsible for the more or less scattered adverse effects of hazardous chemicals, be it effects on the environment or on European citizens. It is also not clear how the task of gathering data and testing chemicals is to be divided between industry and authorities. Finally, the question is if it is the responsibility - and incontestable right - of politicians assisted by environmental and health authorities to determine the total acceptable level of chemicals production, use and discharge?

**Failure to comply with international conventions**
The chemicals policy of the EU should enable Member States to comply with international conventions. However, the “Generation target” - an important international obligation to cease the emissions of hazardous substances to the Northeast Atlantic before 2020 - which was adopted by the special ministerial meeting of the OSPAR Commission in 1998, has not been incorporated into chemicals policy at the EU level although this is a prerequisite for its success.
Proposals for the new strategy

The EU consists of major industrial nations with an extensive use and production of chemicals. As such the EU has a very important role on the global scene in determining the weight of future problems related to environment and health. Recent developments in the EU point towards a growing awareness of the need to reprioritise the EU chemicals policy.

Good legislation encourages positive actions within industry and among retailers and consumers. However, legislation is not the only driving force in the improvement of the chemicals situation. The chemicals industry could have a very important role to play by taking the lead in a more sustainable production of chemicals. Environment and consumer organisations and workers unions can also be an important driving force by putting pressure on retailers, industries and politicians.

A whole new framework directive on chemicals might be a solution for the new strategy, but this should not cause urgently needed changes in legislation and practice to be further delayed. It is important that the new strategy include both short-term and long-term objectives, and it must be both detailed and wide-ranging since industrial chemicals are used in numerous products and in relation to a wide range of different activities in society.

Overall objectives and guiding principles

The most important overall objectives of the new chemicals strategy must be to phase out substances that present unacceptable hazards and to establish an adequate overview of all chemicals on the market. As the three main guiding principles, the strategy must be based on the precautionary principle, the principle of substitution and the public right to information and participation. However, it is not enough for a new strategy to only set up long-term objectives and idealistic principles.

The principles have to be implemented in practice, and below a number of suggestions for practical improvements to the current directives are presented. One rationale behind these proposals is that improvements made to the procedures of classification and risk assessment will have a spill-over effect on regulation and risk management and speed-up the whole process (Figure 3).

If the proposals presented in this Chapter are combined with an adequate integration of the chemicals strategy with environment and consumer policies, this could contribute significantly to the development of a sound strategy for the future chemicals policy.
Proposed guidelines for the new chemicals strategy

**Overall objectives**
- Phase out substances with unacceptable effects on the environment or human health.
- Reduce the amount of chemicals on the market to the safe ones.
- Provide knowledge on all chemicals on the market.

**Guiding principles**
- The Precautionary Principle
- The Principle of Substitution
- The public right to know and participate

**Practical changes to procedures**

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## Proposals for speeding up assessment and classification procedures

In the future only adequately assessed chemicals should be accepted on the market. All hazardous chemicals must be classified, and classification criteria must be developed for all relevant adverse effects. The proposals below should be co-ordinated with intensified research to set up reliable tests for properties for which there are no standardised test today such as endocrine disruption and persistence in the marine environment.

### Set up deadlines for assessment of existing chemicals

A final deadline should be set up for non-assessed chemicals. The chemicals industries have made a voluntary commitment to provide data for approx. 1,000 HPV (High Production Volume) Chemicals before 2005 (see next section). However, the protection of consumers and the environment in the EU should not rely only on voluntary schemes. A better approach would be to set up legally binding deadlines implying that all chemicals not assessed by the deadline will be removed from the market until a proper assessment is in place.

The question is how long we should accept non-assessed chemicals on the market and how much time it is reasonable to offer the chemicals industries to get the assessments done? A reasonable deadline could be the year 2005 for all HPV chemicals and 2010 for the chemicals produced in lower volumes.

### Use predicted data where no experimental data exist

A partial solution to the global lack of research capacity to perform experimental tests lies with the possibility of using modelled or predicted data. If no experimental data are available, the properties of chemicals may sometimes be predicted by comparative studies of chemicals belonging to the same structural groups. These studies may be more or less simple comparions based on “common knowledge” among chemists about closely related chemicals (group classification). They may also be more complicated calculations based on models derived from databases with data for large numbers of chemicals. These calculations are based on the so-called QSAR approach.

QSAR means: Quantitative Structure-Activity Relationship and will be explained in the illustration below.
The chemical industry, particularly the medical industry, already applies QSAR screenings for many different purposes, and some authorities have also used QSAR for predicting properties of non-assessed chemicals. In fact, numerous relevant QSAR-results already exist for non-assessed chemicals, and many of these data predict that non-assessed chemicals would be classified dangerous if they were assessed.

Not every chemical can be tested by QSAR. It mainly works for discrete organic substances, and not all effects can be modelled. However, it is possible to compute a range of effects such as persistence, ability to bioaccumulate, toxicity to fish and ability to cause cancer with a quite high degree of certainty for up to 50 – 60,000 organic chemicals. We propose that in the absence of experimental data, these chemicals should be classified according to their predicted values.

Efforts should also be made to predict the effects of those chemicals that do not fit into the QSAR models by simply grouping chemicals and comparing structural relationships. In doing so chemicals should generally be classified as the most dangerous of the tested substances in their group. These exercises may cause some chemicals to be over-classified, but in consideration of consumers and the environment the industry should be able to prove these chemicals safe beyond reasonable doubt. In this respect such an approach may be seen as a partial reversal of the burden of proof.

It is important to note, however, that predictions should only be used to identify possible hazards, and not to draw the conclusion that no hazard exists. Moreover, the employment of QSAR should not cause a delay in the work of producing experimental data.
Get answers with QSAR:

1: A scientist wants to study whether or not the chemical substance Ethylpropyl nitrosamine is carcinogenic. The scientist only knows the chemical structure of the substance.

2: (Keying in the substance) The chemical structure is keyed in the model-language SM ILES: CCCN(CC)N=O. In the database lies information on approximately 2000 substances of which a couple of hundreds are used for calculating the probability for carcinogenic effects. The information is based on animal tests.

3: (Comparing) The model compares the unknown substance with similar substances in the database.

4: (Calculation) The model calculates the probability of carcinogenic effects. The test shows that Ethylpropyl nitrosamine is particularly carcinogenic with a probability of 1,000 (i.e. 100%).
Proposals for the new strategy

Improve the self-classification scheme

The self-classification scheme needs fundamental improvement. A better quality control of the classifications performed by producers and importers is needed. The producers should still be responsible for performing the actual classification, but this must be balanced by an effective control system including possible fines by the authorities, if classifications are found to be misleading.

If all available quality-controlled QSAR data were made publicly accessible, producers would be encouraged to improve their self-classifications on the basis of these data. However, the authorities must retain an option to require that new experimental data are generated by industry and to demand independent peer reviews of completed classifications.

Proposals to speed up or leave out risk assessments

The progress from hazard evaluation to risk management must evolve at a much faster pace than it does today. Efforts must be made to deal with the shortcomings listed in Chapter 4, but even if the RAs are improved, elaborate risk assessments should still not be considered prerequisite before banning substances that are known to have severe hazardous properties.

For other substances where risk assessments are upheld, strict deadlines must be set for completion of risk assessment reports and - more importantly - for the completion of risk reduction strategies and their implementation. Risk assessments can be speeded up in various ways, for instance by doing parallel assessments of chemicals used in the same fields of application or by simply allocating more human and financial resources to do the work.

Base restrictions on hazard evaluation rather than full-scale risk assessments.

A main objective of the new strategy should be to aim at a zero risk level with regard to dangerous substances. According to the precautionary principle all substances that are supplied to the general public or released to the natural environment or working environment should be inherently safe. In these cases focus should always be on hazard reduction rather than exposure control.

In closed systems, it may be reasonable to accept the use of dangerous chemicals. However, even closed systems have weaknesses. For instance PCBs have generally been used in “closed” systems, but they are widespread in the environment today.
The new strategy should ensure that persistent and bioaccumulating substances are not released to the environment. Likewise, skin sensitizers, CMRs and other substances that are hazardous to human health should not be found in consumer products. These substances should be subject to total or partial bans based on existing knowledge of their properties and regardless of any predictable risk. Chemicals to be regulated in this manner could be selected by setting up general cut-off criteria for persistence, ability to bioaccumulate and relevant adverse toxic effects. Here, experience can be drawn from the ongoing OSPAR DYNAM EC process of selecting chemicals, which are to be regulated according to the OSPAR Convention, as well as from current developments in the national chemicals policies of the Netherlands and Sweden, where such efforts are already in progress.

The cocktail of toxins within us all

She said:

"I consider myself to have a healthy diet. I eat fresh vegetables, lots of fruit and very little meat. Yet last week I discovered my body is carrying a cocktail of hazardous chemicals. If I became pregnant, they could be passed on to my baby."

Journalist Lucy Johnston after having had a fat sample from her body analysed for toxic pollutants at a London-based medical laboratory. Today, every adult European has up to 500 different industrial chemicals accumulated in their body fat. Most of them are pesticides.

Give all stakeholders equal influence

When drawing up the new chemicals strategy it is paramount that the Commission and the Member States are fully aware of the importance of balancing the influence of all stakeholders. The chemicals industry has a legitimate right to seek influence on chemicals policies, and the industry’s professional knowledge of chemicals and their properties is a resource. However, environment and consumer concerns are best expressed by organisations representing these specific interests. Environment and consumer organisations should therefore be able to participate in the process on equal terms with industry.

To the extent that risk assessment procedures are upheld, the chemical industry should take part in the work, but apart from providing (objective) data, their involvement in the decision-making should be limited. The chemicals industry could also perform hazard assessments and preliminary suggestions for risk assessments, but care should be taken that only independent scientists participate in drawing the conclusions of risk assessments.

The global chemicals industry as represented by The International Council of Chemical Associations (ICCA) has taken the initiative to perform hazard screenings for approximately 1,000 HPV chemicals before the end of 2004. These screenings include the so-called SIDS data set following guidelines decided by the OECD. In addition, CEFIC (European Chemicals Industry Council) has taken the initiative to carry out preliminary risk assessments. The ICCA and CEFIC initiatives are likely to be decisive for the extent of regulatory measures adopted in the EU. It is therefore vital that this work is completed and reviewed by independent experts as soon as possible. In the meantime, it is important that the work done by ICCA and CEFIC does not postpone adequate action on the EU level.

Protection of vulnerable groups

“Children are not “little adults” but are particularly vulnerable to pollutants because of their immature biological development; behaviour; metabolism; greater exposure to pollutants, relative to body weight and longer life at risk than adults.” (EEA, 1999b)

A future chemicals policy must take considerations of children, pregnant women, elderly people as well as those who are not healthy and fit. Vulnerable groups need particular protection from harmful chemicals.
Proposals for a tightening of regulation procedures

The regulatory system must handle both single substances and combined effects.

The procedure for regulating and banning chemicals certainly needs to be tightened. The regulatory system must be able to ensure safe production and use of all hazardous substances and preparations on the market and to handle the combined effects of all harmful chemicals.

Phase-out undesirable substances

If it is recognised that hazardous chemicals should be regulated based on their intrinsic properties leaving out the elaborate risk assessments as described in the previous section, this will imply that the work of imposing bans on chemicals will be intensified. Bans are often introduced after a certain warning period, allowing the affected industries some time to develop alternative methods. This approach is reasonable given the fact that the industrial sector holds enormous human and economic capacities for research and development. In the future these resources should be dedicated much more to developing new technologies and products - based on non-toxic and non-persistent chemicals - for the benefit of the citizens of Europe and our environment. However, to achieve this, an unflinching environmental policy is needed that dares to challenge the industry. Moreover, the question is whether bans are not often a better solution for industry than voluntary schemes. Bans give all producers equal opportunities and do not lead to unfair competition.

The Principle of Substitution

The principle of substitution aims at substituting harmful chemicals with less harmful alternatives, such as substances that do not persist or bioaccumulate. It is important that once a less harmful substance or material has been acknowledged, the old substance or material is no longer allowed. Today, industry is under no obligation to use the safest chemicals.

The new chemicals strategy should devise new ways of integrating the substitution principle into practical legislation and administration. Practically this can be done in e.g. approval schemes, Integrated Product Policy and when providing public information, but naturally the producers and importers are still the most important agents in implementing the principle of substitution.
Gradually expand the approval scheme approach

Today most chemicals are regulated via a "negative list system". Substances are marketed freely unless authorities impose a ban or certain restrictions. Only pharmaceuticals, pesticides, biocides and food additives must be approved before they can be placed on the market. In the long term a number of additional product groups should be made subject to approval schemes.

Approvals should generally be given for specific time periods and specific uses only. The first targets should be products of concern for which substitution by more environment and consumer friendly substances is already possible (e.g. detergents, fragrances, cosmetics, paints and varnishes).

Approval schemes require many resources within the administrative system, and in themselves the schemes do not guarantee that no hazardous chemicals are marketed. On the contrary, the schemes may have the effect of justifying the use of hazardous substances. However, one positive consequence of the current approval schemes is that the total number of marketed chemicals in each product group can be reduced considerably, even by a factor of 10, without restricting the users'/consumers' freedom of choice between different chemical 'options' (Bro-Rasmussen, 1999).

Moreover adequate data on both hazards and production volumes should be a precondition for authorising chemicals, and effective approval schemes will make it feasible to apply both the principle of precaution and the principle of substitution when products are evaluated. (The principle of substitution has already been included in the Biocides Directive, where comparative assessments must be performed to establish which chemicals are best for any purpose).

To sum up, the new chemicals strategy should include efforts to design flexible and effective authorisation bodies with adequate resources allocated to the relevant authorities. In doing so, it is important to limit the transition period. The backlog will not be solved automatically unless a deadline is set by which all chemicals must be reviewed by the authorising bodies.
Integrated Product Policy

- A new approach in environmental policy

Restrictions and bans are not the only available instruments to control the production and use of industrial chemicals. The process of developing “Integrated Product Policy” (IPP) has offered a useful catalogue of additional instruments that can be applied both nationally and at the EU level. The overall objective of IPP is to limit the market for harmful products. This can be done through a variety of incentives including legally binding regulations as well as voluntary schemes.

The aim is to integrate environment considerations into products and processes as early as possible in the development phase. This integrated approach also enhances product safety as related to consumers and limits the problems related to waste disposal. Some Member States have already formulated their national IPP strategies and the issue has also been raised at EU level.

The Directorate of the Environment is drawing up a green paper on IPP, to be presented in the first semester of 2000. This will provide a good chance of having plans for IPP integrated with the planned revision of the chemicals strategy.

Major elements of IPP are:

- Public access to information
- Extended producers’ responsibility
- Restructured standardisation procedure
- Development of Best Available Technology (BAT)
- Green public procurement
- Eco-labelling
- Green taxes
- “Closed loop” systems of production, consumption and disposal

As yet it is not quite clear exactly what IPP encompasses and how the ideas of IPP are translated into practice. There is a danger that IPP may lead to more soft policy measures, creative pilot projects, and consensual dialogue - which in turn could make authorities gradually withdraw from their role as regulators to become mere moderators or facilitators. However, if used in an effective way, the key elements of IPP can definitely be of use in the struggle to achieve an acceptable level of chemicals production in the EU.
Consumers have a full right to know what chemicals are in which products

All Member States should establish a product register, which, as a minimum, should encompass products that contain "substances of concern". Moreover, easily accessible public information services on harmful chemicals should be made available. This information should include a list of priority undesirable chemicals and a list of products that contain these chemicals as well as information on possible alternatives for substitution. There should be various levels of information, so that it would be useful both to the general public and to scientists.

Restructured standardisation procedures

Environment and health authorities should establish reasonable ranges for the standardisation organisations to work within. Authorities could decide on e.g. the maximum content of harmful chemicals in products or maximum persistence of chemicals in preparations. Subsequently the standardisation organisations could establish the technical details within these frameworks.

Green taxes

The OECD has recommended green taxation as an effective tool towards reducing the production of harmful chemicals. Green taxes do not necessarily imply a heavier tax load on the ordinary citizen. They could be made part of a green tax reform, where higher taxes on harmful chemicals and natural resources are combined with lower income tax. Today, the market prices do not cover the costs of pollution and health damage. These are paid by the taxpayers, victims and the general public. Green taxes on chemicals are one way of implementing the "polluter pays" principle (EEA, 1996 and 1998).
The 20th century has changed our interaction with nature to a point where the human influence on
nature is awesome, global and without precedent. Industrial chemicals have played an important role
and we are only beginning to see the effects of industrial chemicals on eco-systems and our own
bodies.

It’s time to act. Chemicals policy is not just a minor part of the environmental and health policy.
Chemicals policy is relevant for all the products we come across in our every-day life. Allergy, hormone
disruptions in wildlife, depletion of the ozone layer etc. can in many cases be related to the poor
functioning of the chemicals policy. Therefore, in the search for good health and a safe environment,
chemicals policy is a wise area to start making fundamental changes.

• Ideally, a sustainable use and production of chemicals would require all synthetic chemicals to
  break down rapidly in nature into harmless, natural substances, so that no accumulation of
  man-made substances in products, human bodies or the environment would occur.

• An informed chemicals policy requires a continuous and comprehensive communication between
  producers, citizens, scientists, regulators and policy-makers. It is not enough to change legislation
  and administration. It is also essential to strengthen the public debate in the EU on the chemicals
  issue. (see e.g. five fundamental demands for the future chemicals policy as presented by
  Warhurst, 2000). The right to know is the incontestable right of EU citizens and a necessary
  prerequisite for the public to make informed choices and participate in the important
  political processes.

• A sound chemicals policy requires that we act with precaution. It is important that all stake-
  holders realise that scientific proof of harm cannot always be obtained. We have to live with the
  fact that decisions must be taken in a world of vast uncertainties where the consequences of not
  taking action against dangerous substances are too serious to justify delayed decision-making.
  This implies that we must give nature and our health the benefit of the doubt.

The facts we face are these: We do not know the effects of the vast amount of man-made chemicals
that surround us, and we cannot find the human and financial resources required to test and manage
all these substances. The ultimate question is then: Are we ready to continue to produce and live
with these chemicals, or should we start acting differently in the years to come?
References


European Commission, DG XI (1998):
Integrated Product Policy – a study analysing national and international developments with regard to Integrated Product Policy in the environment field and providing elements for an EC-policy in this area.

European Commission (2000):

European Environment Council (1999):
Community policy for chemical products – Council conclusions. (Minutes from Council meeting, June 1999).

Express micro edition (January 6, 2000):
Cocktail of toxins in us all. www.lineone.net/express.

Friends of the Earth (1998):
Sustainable use and production of chemicals. Consultation response.

Greenpeace, Denmark (1997)
Letter to Danish EPA. October, 1997.

Greenpeace (Santillo, D. Johnston, P. and Singhoefen, A.) (1999):


Ingenioeren, (Engineering weekly) (1998):

A silent epidemic of environmental metal poisoning? Environmental Pollution 50, 139-162.

OECD (1986):
Existing chemicals, priority setting and chemical reviews.

Estimating the PTB-profile. RIVM report no. 601503 016.

Swedish National Chemicals Inspectorate (KEMI) (1998):
Chemicals policy within the European Union: Minutes of an informal discussion with experts from Austria, Denmark, Finland, the Netherlands and Sweden tabled at the Informal meeting of EU Environment Ministers, Chester.

Swedish Ministry of the Environment (1998):

Swedish Ministry of the Environment (1999):


Van Leeuwen, J. C. et al. (1996):

**Acronyms and glossary**

**BAT**
Best Available Technology.

**Bioaccumulation**
Storage of persistent substances in living tissues with accumulating concentrations in humans or animals of prey.

**CEFIC**
European Chemicals Industry Council, Brussels.

**CMR**
Carcinogenic, Mutagenic, toxic to Reproduction. – Chemical substances, that cause cancer, mutations and/or are toxic to reproduction.

**DYNAMEC**
ad hoc OSPAR working group to develop a "Dynamic selection and prioritisation mechanism" to select those chemicals for which the OSPAR cessation target applies.

**ECB**
European Chemicals Bureau. Ispra.

**EEA**
European Environment Agency, Copenhagen.

**EINECS**
European Inventory of Existing Commercial Chemical Substances.

**ELINCS**
European List of Notified Chemical Substances (list of "new" substances).

**Existing substances**
Substances that were on the market before 1981 and are registered on the EINECS list.

**Harmful substances**
In this paper the term is used in a broad sense for substances that cause "undesirable harm".

**Hazardous**
Commonly defined as "with the potential to cause harm".

**HPV Chemicals**
High Production Volume Chemicals (produced in volumes ≥ 1,000 tons/year per producer/importer).
Special concerns are related to these chemicals because high production volumes are related to high risks.

**ICCA**
International Council of Chemical Associations – a global association.

**IUCLID**
International Uniform Chemical Information Database.

**LPV Chemicals**
Low production volume chemicals (production volumes 10 – 1,000 tons a year).

**New substances**
Substances that were introduced to the market after the completion of the EIN ECS list in 1981.

**NGO**
Non Governmental Organisation.

**OECD**
Organisation for Economic Co-operation and Development.

**OSPAR**
Oslo-Paris Convention for the protection of the marine environment of the North East Atlantic.

**PEC**
Predicted Environment Concentration.

**Persistent substances**
Substances that do not break down in nature – or break down very slowly.

**PNEC**
Predicted No-Effect Concentration.

**POP**
Persistent Organic Pollutants, Subclass of PTBs that are prone to long range atmospheric transport and can result in adverse environmental and mammalian toxicity near or far from their source.

**PTB**
Persistent, Toxic, Bioaccumulating.

**QSAR**
Quantitative (or Qualitative) Structure-Activity Relationship. Models used to predict the qualities of chemicals.

**RA**
Risk Assessment.

**SIDS**
Screening Information Data sets, following OECD guidelines for hazard screening.

**UNEP**
United Nations Environment Programme.
Annex 1

- Key elements of central legal acts

**Directive 67/548**
**Classification and Labelling of Dangerous Substances**
The key elements of the directive are:
1. Classification and labelling of chemicals according to their intrinsic dangerous properties. There are 15 classes of danger such as “explosive”, “very toxic”, “carcinogenic” etc.
2. Notification of “new” chemicals prior to marketing. Since 1982 the importers and producers of substances are obliged to submit information to the authorities before a new substance is placed on the market. Only 2,400 “new” substances have been notified according to the directive, and these are mainly substances in small market volumes of 100 tons or less.
In Annex 1 to this directive 4,800 substances have been classified according to their health effects and approximately 2,000 substances have been classified according to their environmental effects. The Directive is permanently updated to take account of scientific and technical progress in the knowledge of dangerous substances. However, as shown in this paper the progress is unacceptably slow from an environment and consumer point of view.

**Directive 88/379**
**Classification and Labelling of Dangerous Preparations**
This directive sets out harmonised rules for the classification, packaging and labelling of dangerous preparations (intentional mixtures). This directive uses the same categories of danger, the same criteria for labelling, the same labelling scheme, the same test methods and the same packaging rules as Directive 67/548, but there are no requirements to notify new mixtures. The directive was revised in May 1999, and classification and labelling of preparations with regard to the environment was introduced, but will only be obligatory from 2002.

**Directive 76/769**
**Marketing and use restriction**
This directive is known as the “Limitations Directive”. Restrictions under this directive generally take the form of controlled use i.e. they restrict the substance for particular uses only. Up to date the directive has been amended 18 times providing restrictions on 42 substances or groups of substances covering a total of about 900 individual substances. Most of these are cancer-causing substances banned for consumer use. Initiatives to harmonise under this directive may come from many sources. In the future it is expected that an increasing number of risk reduction measures may arise from Regulation 793/93.

**Regulation 793/93**
**Evaluation and control of the risks of existing substances**
Generally known as the “Existing Substances Regulation”. It was developed in response to the Fourth Community Action Programme on the Environment (1987-1992). Between 1994 and 1997 a total of 110 chemicals have been selected for risk assessment. For each substance a Member State has taken the responsibility to draft a risk assessment report covering:
- Hazard assessment: intrinsic properties of the substance
- Exposure assessment: sources and emissions, environmental, occupational and consumer exposure.
- Dose-response assessment: relationships between exposure and harmful effects
- Risk characterisation: Prediction of PNEC (Predicted No-Effect Concentration) and PEC (Predicted Environment Concentration). If PEC is larger than PNEC, “concern” is the conclusion.

The final risk assessment report can draw one of three standard conclusions. The conclusions may be:
- more information needed,
- no concern and
- concern, risk reduction is needed.
If conclusion ii, is reached a risk reduction strategy has to be agreed upon by the Member States.

Please Note:
The Directives are all so-called “total harmonisation directives”, which means that Member States as a primary rule cannot impose further limitations nationally. (Regulation 793/93 is passed in reference to Article 95, which also means total harmonisation). However, it is important to note that Member States can adopt national regulations on substances that are not listed in the Annex 1 of the Limitations Directive 76/769 but they have to notify the Commission with a justification. Subsequently, the Commission decides if the Member State has justifiable ground for a national regulation or if new legislation on EU-level should be proposed. If the Commission does not accept the justification, the notification is rejected and the case may end up in court.
The main objective of the convention is to stabilise climate-emissions by human activity at levels that do not create threatening climate-changes.

Regulation of a number of ozone-layer depleting substances (CFCs, halons, carbon tetrachloride, 1,1,1 trichloromethane, HCFCs and methylbromide).

Information procedure for the exporting of 27 chemicals that are prohibited or strictly regulated in the exporting country. Will enter into force when ratified by 50 countries.

Phasing out and regulation of POPs (persistent organic pollutants). First step is to phase out 12 named POPs. Expected to be adopted by spring 2001.

Control trans-boundary movements of hazardous waste and their disposal.

Convention of the protection of the marine environment of the North East Atlantic.

The Generation Target was agreed on in the Esbjerg Declaration in 1995 and adopted by the OSPAR Convention in 1998. The aim is to eliminate releases of persistent, toxic and bioaccumulating substances to the North East Atlantic over 25 years, i.e. before 2020.

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<th>Content</th>
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<td>1994</td>
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<td>Montreal Protocol</td>
<td>1989</td>
<td>Regulation of a number of ozone-layer depleting substances (CFCs, halons, carbon tetrachloride, 1,1,1 trichloromethane, HCFCs and methylbromide).</td>
</tr>
<tr>
<td>PIC Convention</td>
<td></td>
<td>Information procedure for the exporting of 27 chemicals that are prohibited or strictly regulated in the exporting country. Will enter into force when ratified by 50 countries.</td>
</tr>
<tr>
<td>POP Convention</td>
<td></td>
<td>Phasing out and regulation of POPs (persistent organic pollutants). First step is to phase out 12 named POPs. Expected to be adopted by spring 2001.</td>
</tr>
<tr>
<td>OSPAR Convention</td>
<td>1998</td>
<td>Convention of the protection of the marine environment of the North East Atlantic. The Generation Target was agreed on in the Esbjerg Declaration in 1995 and adopted by the OSPAR Convention in 1998. The aim is to eliminate releases of persistent, toxic and bioaccumulating substances to the North East Atlantic over 25 years, i.e. before 2020.</td>
</tr>
</tbody>
</table>

More information on international conventions:
www.unep.ch/ozone/home.htm
www.unfccc.de/
www.unep.ch/basel
www.ospar.org
A European NGO-campaign on chemicals policy.

This policy paper is a part of a broader NGO campaign on chemicals policy, run by The Danish Society for the Conservation of Nature, the Danish Ecological Council and the Danish Consumer Council in co-operation with EEB (European Environmental Bureau) and BEUC (European Consumers’ Organisation) as a response to the ongoing revision of EU chemicals policy.

The objectives of the campaign are:

• To move the chemicals policy in the EU towards better control of hazardous chemicals and implementation of the precautionary principle in common rules and regulations of the EU.
• To strengthen the co-ordination between European NGOs concerning the EU chemicals policy.
• To strengthen European public knowledge, awareness and debate on the environmental and health-related risks associated to the use of industrial chemicals.

The campaign includes 4 central elements:

• This policy paper, which is distributed to NGOs and EU decision-makers.
• The newsletter - Chemical Awareness -, which provides updates on the latest essential developments and debates on essential issues, related to chemicals and chemicals policies. The newsletter is available at www.dn.dk/chemaware.
• A conference on EU chemicals policy is planned in October 2000 in Copenhagen.
• A short popular version of this policy paper will also be produced.

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However, the final responsibility for this paper lies with The Danish Ecological Council.
Nobody knows the damage being caused to the human body from the
tens of thousands of chemicals that surround us. Nobody knows the
extent of the damage that these chemicals will cause to the environment.
The extraordinary and shocking reality is that most of these chemicals
have never been tested, yet most are used daily by European industry to
make the kinds of products we 'enjoy' every day of our lives. Did anyone
tell us of the risks we are taking? That's because nobody knows just what
the risks are.

It's time for awareness. It's time for action. It's time to put these chemicals
under the microscope. We cannot wait. Our lives, the lives of our children,
the life of the planet are on the line.

2000 must bring a New Approach to Chemicals in the EU

- Testing for all chemicals
- What are the risks?
- What are the benefits?
- Ban unsafe chemicals
- Support safe chemicals
- Act for safety
- Act now
- Put chemicals under the microscope

This paper is part of a broad campaign on chemicals policy, run by the Danish Ecological Council, Danish Society for the Conservation of nature, Danish Consumer Council, EEB (European Environmental Bureau) and BEUC (the European Consumers' Organisation), as a contribution to the ongoing review of the EU Chemicals policy.

This paper gives a brief overview of the current situation, presents a number of proposals for a new chemicals strategy and calls for a reduction in the total number of non-assessed chemicals on the market and a phasing out of chemicals with unacceptable effects on the environment and human health.