



**Friends of the Earth  
Les Amis de la Terre  
Europe**

**European Commission's White Paper:  
"*Strategy for a future Chemicals Policy*"  
COM (2001) 88 Final**

**Response from Friends of the Earth Europe**

**May 2001**

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## 1. Executive Summary

Friends of the Earth Europe is very disappointed with this White Paper, and considers that it will fail to ensure a high level of protection for humans and the environment.

In Friends of the Earth's view, the main deficiencies of the White Paper are:

- The authorisation system could become a license to continue using risky chemicals. It should be made clear that this system is intended to ban risky chemicals, with temporary derogations for specific uses where there is an overwhelming societal need and no safer alternative.
- It provides no mechanism for phasing out the use of chemicals that accumulate in the body and in the environment. Friends of the Earth and the many other NGOs signed up to the Copenhagen Charter are committed to phasing out such chemicals. An earlier draft of the White Paper included a proposal that such chemicals be incorporated into the proposed ban with temporary authorisation regime, but this was removed due to industry lobbying. We believe that there must be a phase out of chemicals that accumulate in our bodies or the environment, regardless of currently understood toxicity, so we don't repeat the disaster of PCBs.
- It fails to deal with hormone disrupting chemicals. The White Paper claims that they will be dealt with because of restrictions on proven reproductive toxins, yet, in reality, due to the large amount of research required to establish this, the majority of proven hormone disrupters will not be restricted through such a mechanism for many years, if at all, so exposure will continue. This is certainly not precautionary.
- It does not contain clear, firm deadlines for delivery of safety data, after which chemicals must be removed from the market. Its deadlines are also weaker than those proposed in Sweden's new chemicals policy.
- It does not control import of chemicals within products; it is unscientific and unsafe to exempt such chemicals from proper safety assessment.
- It does not properly enforce substitution, as it states that substitution is only required for substances already shown to be 'dangerous', whilst we - and in our view the public - believe that industry should always be obliged to use the safest chemicals.
- It is vague in its commitment to public right to know. Right to know should have two elements, a right to know all the safety data about the chemical - there is no justification for commercial confidentiality - and the right to know what chemicals are used in the products we buy. Such a right to know will ensure that the supply chain is open and transparent, and allow individuals to make decisions on what chemicals they are exposed to.
- It is unclear about resourcing, particularly for key tasks such as the independent reviewing of industry data, and the resources necessary to enable Member States and the central authority to evaluate the safety of chemicals. In addition, the level of safety assessment is based on tonnages per producer, which is arbitrary and has no scientific justification; it should be based on overall tonnages.
- It has insufficient regard to the need to minimise animal testing, which can be achieved through adoption of the Copenhagen Charter policies: phasing out chemicals that are persistent or bioaccumulate, an obligation to use the safest chemicals, and only using chemicals if their use is safe beyond reasonable doubt, where doubt can be shown by in vitro or QSAR methods.

It is essential that Member States and the European Parliament use their powers to correct these faults in the Commission's proposed new chemicals policy.

## 2. Introduction

Friends of the Earth welcomes the publication of the European Commission's White Paper on Chemicals, as we consider that the current system for regulating the production and use of chemicals is grossly inadequate. However, we consider that the White Paper has a number of crucial deficiencies that must be remedied in order to ensure a high level of protection for human health and the environment.

We consider that technology-forcing regulation must be used to move the chemical industry away from its current dependence on using poorly understood chemicals, some of which accumulate in our bodies or the environment, or have hormone disrupting properties. The chemical industry has proved itself incapable of taking a responsible approach to the chemicals it produces, and it is the responsibility of governments and regulators to ensure that public health and the environment are protected, now and in the future.

If a precautionary approach is not taken then there will be a continuing reduction in public confidence in the regulatory system. In particular, Friends of the Earth's Crisis in Chemicals report<sup>1</sup> predicts that the biomedical revolution will substantially advance our understanding of the toxic impacts that some chemicals have on our bodies, and will identify particularly susceptible individuals. These discoveries will have a significant impact on the regulation and use of chemicals in the future.

We have been working with consumer and environmental organisations across Europe to formulate our key requirements for the EU's new chemicals policy. These requirements are laid out in the Copenhagen Charter:

- 1) A full right to know, including which chemicals are present in products.
- 2) A deadline by which all chemicals on the market must have had their safety independently assessed. All uses of a chemical should be approved and should be demonstrated to be safe beyond reasonable doubt.
- 3) A phase-out of persistent or bioaccumulative chemicals.
- 4) A requirement to substitute less safe chemicals with safer alternatives.
- 5) A commitment to stop all releases to the environment of hazardous substances by 2020.

Supporters of the charter include Friends of the Earth Europe, WWF Europe, the European Environment Bureau, the European Consumers Organisation BEUC and the Danish Environment Minister Svend Auken.

This response is separated into four sections, the scope of the strategy, producer responsibility, administration and resources and finally, animal testing.

In addition to the specific concerns described in this document, Friends of the Earth is unhappy with the vagueness of much of the wording of the White Paper, which means that many parts of the paper can be read in several different ways. We consider it vital that the Directive which is drafted following on from this White Paper is as clear as possible on issues such as how risk assessments are carried out, by whom and to what level they will be reviewed.

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<sup>1</sup> Warhurst, A.M., *Crisis in Chemicals: The threat posed by the 'Biomedical Revolution' to the profits, liabilities, and regulation of industries making and using chemicals*, 2000, Friends of the Earth, London, UK. [http://www.foe.co.uk/resource/reports/crisis\\_chemicals.pdf](http://www.foe.co.uk/resource/reports/crisis_chemicals.pdf)

### 3. Scope of the strategy

Friends of the Earth welcomes many aspects of the proposed REACH system. However, there are many deficiencies in it, and in other aspects of the White Paper. Our main concerns relating to the scope of the strategy are outlined below, and we consider that these concerns must be dealt with for the strategy to properly ensure a high level of protection for health and the environment, reflecting the precautionary principle and the principle of sustainability. We also believe such measures are essential to create an internal market that will be supported by the EU's consumers.

We believe that the new Swedish chemicals policy provides an excellent model for the whole EU system.

We also consider that it is essential for the long-term competitiveness of the EU chemical industry, and the other EU industries that use chemicals, that the chemical industry is forced away from its past reliance on risky chemicals. The future lies with greener chemicals and processes, and the EU chemical industry will only be competitive in the future if it invests in these areas. The chemical industry has been unwilling to work towards sustainability; a new EU chemicals policy will help force the industry to look to the future, not the past.

#### 3.1 The registration system

- (i) The registration system does not contain clear, firm deadlines for delivery of safety data, after which chemicals must be removed from the market if data has not been delivered; we consider such deadlines are essential. Its deadlines are also weaker than those proposed in Sweden's new chemicals policy. We believe strict deadlines are achievable; see also the 'Animal Testing' section on page 12.
- (ii) We are concerned that the registration system does not prioritise rapid gathering of preliminary data on all chemicals, in particular, data on persistence and bioaccumulation, information from computer modelling (QSAR) and *in vitro* techniques, and a list of intended uses. Such data could be rapidly obtained and be immediately available to inform risk reduction.
- (iii) The level of safety assessment for each chemical proposed in the White Paper is based on tonnages per producer or importer. This system is arbitrary and has no scientific justification; for example it is possible to have 5 producers of 900 tonnes per annum of a chemical, yet it will be assessed as if less than 1000 tonnes per annum were produced. Assessments should be based on overall tonnages.
- (iv) We support the proposal that manufacturers or importers must specify intended uses of their products; this must be coupled with a requirement for downstream users to inform the authorities if they wish to use the chemical in a use which was not addressed in the preliminary risk assessment.
- (v) We support the proposal that the registration process will apply to all substances produced within, or imported into, the EU, as it is important to ensure that all chemicals being exported from the EU have had their safety properly assessed.

#### 3.2 The authorisation system

- (i) It is important that the authorisation system does not become a license to continue using risky chemicals. It should be made clear that this system is intended to ban risky chemicals, with temporary derogations for specific uses where there is an overwhelming societal need and no safer alternative.
- (ii) The authorisation system is not currently proposed to cover chemicals that are persistent, bioaccumulative and toxic, or those that are very persistent and very bioaccumulative. It therefore provides no mechanism for phasing out the use of chemicals that accumulate in the

body and in the environment. Friends of the Earth and the many other NGOs signed up to the Copenhagen Charter are committed to phasing out such chemicals. An earlier draft of the White Paper included a proposal that such chemicals be incorporated into the authorisation regime, but this was removed due to industry lobbying, whilst similar provisions exist in Sweden's new chemicals policy. We believe that there must be a phase-out of chemicals that accumulate in our bodies or the environment, regardless of currently understood toxicity. We strongly believe that the public want regulators to protect them from such chemicals, and that they should be incorporated in the authorisation regime.

- (ii) The authorisation system fails to deal with hormone disrupting chemicals. The White Paper claims that they will be dealt with because of restrictions on proven reproductive toxins. In reality, however, due to the large amount of research required to establish this, the majority of proven hormone disrupters will not be restricted through such a mechanism for many years, if at all, so exposure will continue. In addition, many hormone disrupters would not be expected to be reproductive toxins, as they disrupt other hormone systems. The approach to hormone disruption in the White Paper is irresponsible, not precautionary. Hormone disrupters must be brought into the authorisation system.
- (iii) We also consider that the authorisation procedure should be available as a control mechanism for other substances which are assessed as being of high concern, as the authorisation system will be able to block all unauthorised uses, thus providing a higher level of protection than the current Marketing and Use Directive (76/769), which can only restrict named uses.

### **3.3 Controls on chemicals imported in products**

- (i) The White Paper does not control import of chemicals within products. In Friends of the Earth's view, chemicals imported into the EU within products should be treated in the same way as other chemicals; it is unscientific and unsafe to exempt such chemicals from proper safety assessment. Arguments may be made that this will be difficult to enforce; many laws and regulations are difficult to enforce, but this is not a good reason not to make them. Businesses, particularly large companies, will generally try to obey the law, even if it is difficult to enforce. The EU has a duty to protect the health of its citizens and the environment, which requires proper assessment of the safety of all industrial chemicals on sale in Europe, whether they are present in imported products or not.

### **3.4 Substitution**

- (i) The White Paper does not provide any mechanism to enforce substitution, other than for chemicals within the authorisation system. Substitution is a crucial part of a precautionary regulatory approach, whereby chemicals with more hazardous properties are replaced by those with low hazard. There should be a general duty on professional users (including the consumer products industry) to use the safest available chemicals - in our view this is what the public would expect the regulatory system to enforce.
- (ii) We consider that the publication of a list of more hazardous chemicals, such as the Swedish 'Observation List' is an effective way of providing industry with information to assist substitution.
- (iii) When decisions on substitution are particularly problematic we believe a provision for comparative assessment should be introduced.

### **3.5 Right to know**

- (i) The White Paper is vague in its commitment to public right to know. Right to know should have two elements, a right to know all the safety data about the chemical - there is no justification for commercial confidentiality - and the right to know what chemicals are used in the products we buy.

- (ii) Friends of the Earth welcomes the proposals for an internet-based system for providing safety data on chemicals. However, we are concerned that the White Paper does not deal with the problem of commercially confidential safety data; this is discussed in more detail under the 'Animal testing' section on page 12. All safety data must be made publicly available.
- (iii) The White Paper has no provision for providing a more general right to know what chemicals are present in products; this right to know would not necessarily have to include quantitative information. Such a right to know will ensure that the supply chain is open and transparent, and allow individuals and companies to make decisions on which chemicals they use or are exposed to. We do not accept the commercial confidentiality arguments against such a right to know. In reality, in many cases, commercial competitors are able to use analytical techniques to establish composition. Consumers, regulators, citizens groups and smaller companies do not have the resources to do such analyses and should have a legal right to the information; there is no such right in law at the moment. We are not calling for products to be labelled with all the chemicals they contain, but rather for the information to be available on request.

### **3.6 Goals of the strategy**

- (i) The strategy does not provide a mechanism for implementing the OSPAR Convention's generational goal to cease discharges, emissions and losses of hazardous substances to the marine environment by 2020. It also fails to incorporate goals for removal of contamination of other parts of the environment. For example, Friends of the Earth would propose a goal to *"eliminate, or reduce to levels as low as practicable, exposure to all chemicals which contaminate breast milk or body fat, and to those that cross the placenta"*.

## 4. Producer responsibility

Friends of the Earth has many concerns about the nature of producer responsibility in the White Paper. A problem with commenting on this aspect of the White Paper is that several aspects of the paper can be read in different ways, e.g. the paper is not clear as to who will carry out risk assessments on chemicals of more concern.

As a fundamental principle, Friends of the Earth believes that the chemical industry has shown itself incapable of making decisions on the overall safety of its chemicals. It has proved that it is not capable of taking risky chemicals off the market if they are profitable.

### 4.1 Avoiding conflicts of interest

- (i) There is increasing concern across the EU about the damage that can be done by conflicts of interest within governments. Such damage has occurred numerous times in the UK, for example with the response of the Ministry of Agriculture, Fisheries and Food (MAFF) to the BSE crisis. This is leading to increasing separation of regulatory and promotional functions, for example the transfer of the EU's Scientific Committees to DG Health and Consumer Affairs.
- (ii) Friends of the Earth therefore finds it surprising and unacceptable that the EU is considering creating an even more dangerous conflict of interest by delegating risk assessment and risk reduction decisions to the chemical industry. Clearly, the chemical and other industries must retain liability for their products, and will be expected to carry out their own risk assessments as applicable; however, it is not acceptable for regulatory risk assessments to be devolved to industry.
- (iii) In addition, Friends of the Earth considers that it is unacceptable for the EU department that has responsibility for sponsoring the chemical industry to also have a regulatory role. We therefore consider that DG Enterprise should have regulatory responsibility removed from its remit.

### 4.2 Responsibility for generation of hazard data

- (i) Friends of the Earth supports the White Paper's proposals for industry to generate hazard data on their chemicals, subject to the provisos describe in 'Animal Testing', see page 12.

### 4.3 Responsibilities for risk assessment

- (i) Friends of the Earth supports the White Paper's proposal that industry provides a preliminary risk assessment, i.e. a compilation of hazard, use and exposure information. However, this assessment must be checked by the enlarged European Chemicals Bureau.
- (ii) Friends of the Earth opposes the production of risk assessments of chemicals by the chemical industry. Such assessments should be done by, or on behalf of, public authorities, though using money collected from industry. We believe that the European Chemicals Bureau should collect a fee for assessing a chemical from the industry concerned. If the chemical is of lower concern, then this fee should be used by a Member State authority to commission a risk assessment from an independent consultant. If the chemical is of higher concern, then its safety should be assessed by Member States, using a system similar to the current one, but with more resources and support from the European Chemicals Bureau.

### 4.4 Burden on the chemical industry

- (i) The chemical industry has been making a profit from selling its chemicals - it therefore has a responsibility to ensure they are safe. The fact that it hasn't already generated safety data on all its chemicals is scandalous, and cannot be allowed to continue.
- (ii) The chemical industry is notorious for exaggerating the cost impacts of regulation. In reality, as long as the regulatory system is based on the Copenhagen Charter, many chemicals will not

need assessment as it will not be economic to continue selling them. The cost of testing is very much dependant on the nature of testing, and how much data is released from the industry's files (see 'Animal Testing', page 12). Industry's continuing secrecy about such data makes it difficult for either the Commission or Member States to calculate the quantity of testing that may be required.

- (iii) Friends of the Earth does not therefore consider that our proposals would put an undue burden on the chemical industry. It must be remembered that the EU provides industry with access to the largest single market in the world, which is soon to grow even bigger. Industry must accept that the EU is also committed to a high level of protection of human health and the environment. The EU also has a responsibility to Governments and populations in the rest of the world to ensure that the chemical industry faces up to its global responsibilities.

## **5. Administration and resources**

Friends of the Earth generally supports the White Paper's proposals on administration and resourcing, though we consider that the White Paper is unclear about some aspects.

### **5.1 Central chemical agency**

Friends of the Earth supports the White Paper's proposal of an expanded European Chemicals Bureau, as long as this is properly resourced and does not lead to a diminution of Member State involvement in the system. There must be sufficient resources to enable the proper reviewing of industry data.

### **5.2 Role of Member States**

We support the continued involvement of Member States in the regulatory process. As mentioned above, we believe they should continue to carry out risk assessments.

### **5.3 Financing of system**

It is essential that this system is properly resourced, with the bulk of the resources coming from the chemical industry, as they are (and have been) profiting from these chemicals.

## 6. Animal testing

Friends of the Earth believes that our policies will result in a reduction in animal testing. We consider that complete openness, tighter regulation, and increased research into alternative, non-animal, testing methods will result in a substantial reduction, and eventual elimination, of animal experimentation, as outlined below.

In addition, we consider that application of our policies will ensure that industry can easily meet the 'no data, no market' deadlines on delivering safety data. The chemical industry's repeated claims that these deadlines are excessively burdensome do not stand up, and are indeed inconsistent with their other repeated claim that they have plenty of safety data on their chemicals.

### 6.1 Increased research and validation of alternative methods

- (i) It is essential that there is a substantial increase in funding of both research and validation of alternative methods. This is not just the responsibility of European-level research bodies, but should be urgently pursued by Member States.

### 6.2 Complete openness on safety data

- (i) The chemical industry repeatedly claims that it has plenty of safety data on its chemicals, but much of it is protected by commercial confidentiality. This position is not acceptable to Friends of the Earth, nor, in our opinion, to the public. All safety data must be publicly available, and the data collection system must ensure that there is no unnecessary duplication of testing either between companies or between countries.
- (ii) Industry tends to raise concerns regarding property rights to data. Whilst we accept that these concerns may have some merit, we do not accept that they are an excuse to keep data secret and force more animal experiments. It is up to governments and the chemical industry to work out how to deal with these property rights, to ensure that the new chemicals regulatory regime includes complete transparency for all safety testing.

### 6.3 A precautionary regulatory system

- (i) It is crucial that safety testing is not considered as an end in itself, but is coupled with a precautionary regulatory system, and tiered to fit into this regulatory system.
- (ii) All safety testing should be tiered, rather than 'tick box', initially focusing on the non-animal methods: persistence and bioaccumulation, existing data, computer-based and *in vitro* techniques, as proposed by Eurogroup for Animal Welfare in their policy<sup>2</sup>.
- (iii) We consider that the Copenhagen Charter proposals will lead to a minimisation of animal testing:
  - *A phase-out of all persistent or bioaccumulative chemicals.* Persistence can be established without animal experiments; bioaccumulation can be determined by simple chemical tests and environmental sampling. Such chemicals will then not have to go through toxicity testing on animals.
  - *The requirement for all uses of a chemical to be 'safe beyond reasonable doubt'* reduces the amount of evidence required to phase-out a chemical. This should prevent more and more animal experiments being done by industry to rescue a chemical from a ban, and could allow 'reasonable doubt' to be created by *in vitro* or QSAR tests. This reduction in the burden of proof for the phase-out of a chemical is a crucial step in enabling these techniques to displace animal testing.

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<sup>2</sup> <http://www.chemical-awareness.com/news.php?nid=123&aid=336>

- *The provision of a deadline for safety assessment* will remove many chemicals from the market without further testing. Industry must pay the full costs of any tests and for an independent assessment of the safety of their chemicals. Similar provisions in pesticides legislation have resulted in many chemicals leaving the market without any testing at all, because industry doesn't consider it financially worthwhile to spend the money necessary to test them.
- *The substitution principle* should lead to the phase-out of a less tested chemical if either low-toxicity alternatives are available or it can be replaced by a non-chemical technique, without any further toxicity testing.