

**REACH: AN UNPRECEDENTED EUROPEAN INITIATIVE
FOR REGULATING INDUSTRIAL CHEMICALS**

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TABLE OF CONTENTS

	<u>PAGE</u>
Summary.....	3
The Precautionary Principle as the Basis for REACH.....	3
REACH.....	5
The 2003 Weakened Version of REACH.....	12
REACH Should Be Strengthened, Not Weakened.....	15
The Global Impact of REACH.....	35
References	37
Acronyms and Abbreviations.....	42

SUMMARY

In February 2001, the European Commission (EC) released a White Paper, REACH 2001, detailing unique and unprecedented legislative proposals for the regulation of industrial chemicals, based on the Precautionary Principle. The object of these proposals was to reverse the escalating incidence of avoidable cancers, a wide range of other industrial diseases, and environmental contamination. However, REACH was aggressively opposed by the European and U.S. chemical industries, and even more so by the U.S. Administration. The EC responded by making major concessions in its October 2003 REACH-based legislative proposals.

This report critically analyzes REACH, and its 2003 revised proposals, and recommends that REACH be strengthened, not weakened. Furthermore, the report urges that regulatory policies of the U.S., and other industrialized nations, be drastically reformed to comply with those of REACH.

THE PRECAUTIONARY PRINCIPLE AS THE BASIS FOR REACH

Under the terms of the 1948 U.N. Universal Declaration of Human Rights, the right to life, and its corollary right to health, are the first and most important of all fundamental rights recognized by many international conventions. Thus, implementary legislation is needed to mandate that considerations of life and health take absolute precedence over economics and trade (1).

One of the earliest scientific and legal expressions of this concept is the "Precautionary Principle," embodied in the 1992 Rio Declaration (2). "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

In the same year, the UN Conference on Environment and Development (UNCED) also invoked the Precautionary Principle in its Biodiversity Convention treaty (3), and in its Agenda 21 report on risks of environmental degradation (4).

In 1993, the European Commission (EC), the European Union's (EU) administrative body, established the Precautionary Principle as a fundamental basis of environmental law (5). This was subsequently accepted as "full fledged and general principle of international law" (6).

The Precautionary Principle was first invoked by the German government at the 1994 Second North Sea Conference, in relation to marine dumping of toxic wastes. Such policies were accepted as clearly preferable to deliberately accepting risks, and then attempting to "manage" them by reducing exposures to levels claimed "acceptable" by self-interested industry and complicit regulatory agencies. Recognizing the

sovereign rights of each nation to set its own levels of sanitary protection, it was emphasized that precautionary policies should constitute the standard principle, and not the current rare exception (Table 1).

TABLE 1: THE PRECAUTIONARY PRINCIPLE (PP) AS THE BASIS FOR REACH

1948: U.N. DECLARATION OF HUMAN RIGHTS

This created the impetus for implementary legislation, mandating that life and death concerns should take absolute precedence over economics and trade.

1992: RIO DECLARATION

This was the earliest scientific and legal expression of the PP, stressing that action to prevent environmental degradation should not be contingent on "full scientific certainty."

1992: U.N. CONFERENCE ON ENVIRONMENT AND DEVELOPMENT (UNCED)

This invoked the PP in its Biodiversity Convention treaty and reports on risks of environmental degradation.

1993: The EC established the PP as a fundamental basis of environmental law.

1994: SECOND NORTH SEA CONFERENCE

Established the PP in relation to marine dumping of toxic wastes.

1997: SWEDISH CHEMICALS POLICY COMMITTEE, "TOWARDS A SUSTAINABLE CHEMICALS POLICY"

This embraced the fullest implementation of the PP ever proposed. This was approved by Parliament in 2001. The law banned POPs, and very persistent chemicals, and set short time limits for their testing and phase-out.

1998: WORLD CONSERVATION UNION

President Chirac proposed increasing powers of the U.N. Environment Program to avoid sovereignty disputes in the global fight against pollution

2001: REACH 2001

REACH incorporated the PP as its basis for risk assessment, and management. However, as REACH is primarily directed to regulating chemicals for which there are substantive scientific data on adverse effects, the term "Precaution and Prevention Principle" is clearly more appropriate than "Precautionary Principle."

By the 1990's, Sweden had established itself as the most environmentally responsible European nation. In 1997, the Swedish Chemicals Policy Committee published a revolutionary document entitled "Towards a Sustainable Chemicals Policy" which embraced the fullest implementation of the Precautionary Principle ever proposed. This was approved by the Swedish Parliament in 2001. These policies shifted the burden of proof of safety away from the public to industry. Industry was required to produce detailed evidence that all new chemicals proposed for use will pose no carcinogenic, mutagenic, or reproductive (CMR) effects, nor adverse environmental impacts, particularly persistence and bioaccumulation. The law also banned persistent organic pollutants (POPs), and other persistent chemicals, such as lead, and required the phasing out of chlorinated parafins, such as plasticizers and flame retardants. Swedish companies were

given five years to test an estimated 2,500 chemicals used in quantities over 1,000t/p.a. for such effects. By 2010, chemicals used in lesser amounts will also have to be tested.

At a 1998 meeting of the World Conservation Union, President Jacques Chirac proposed increasing the powers of the U.N. Environment Program to avoid sovereignty disputes that hamper the global fight against pollution. President Chirac warned that countries were holding on to outdated concepts of sovereignty, while environmental pollution ignores national borders.

REACH

In the EU, only the EC has the authority to initiate legislation. Responsibility for chemicals management is shared by the Directorate General Environment, and the Directorate General Enterprise. In 1998, the two Directorates began to draft legislation on industrial chemicals. Contrary to general understanding, the impetus for this initiative was not the Precautionary Principle. Instead, it was the fundamental inconsistency between the absence of regulations for industrial chemicals, in striking contrast to the detailed regulations for "substances," including pesticides, food additives, and pharmaceuticals. Most of the latter regulations had already been passed, and were in fact completed by the end of 2000. The draft legislation was thus responsive to World Trade Organization (WTO) rules for non-discriminatory regulations for the manufacture of chemicals (producers), and substances (products).

In a February 2001 "White Paper, Strategy for a Future Chemicals Policy" (7), the EC recommended that regulations known as REACH (Registration, Evaluation, Authorization of Chemicals) be administered by a European Chemicals Bureau (ECB). The regulations were intended to replace some 40 existing directives on the manufacture and import of industrial chemicals in all its originally 15, currently an amalgam of the highly diverse 25 nations of the "new European Union." The procedures, detailed by REACH, embody the Precautionary Principle as the basis for risk assessment and management (8), and for assessing and balancing the externalized costs of industry and the internalized benefits to the public of regulation.

It should, however, be stressed that the Precautionary Principle, historically and scientifically, is and should be restricted to new technologies and new chemicals for which there are no available data on their public health and environmental impacts. Under these circumstances, it is the responsibility of the industry concerned to generate and publish such data, as an essential precaution before any regulation can be considered (1). However, this is clearly not the case for REACH, which relates to the assessment of substantive data on adverse effects. In these circumstances, as is the case for REACH, the term "Prevention Principle" is more appropriate than the "Precautionary Principle," even recognizing the fact that the latter has become embodied in the EU regulatory process (Table 1).

It was anticipated that the REACH proposals would be formally presented to the European Parliament and Council of Ministers after the May 2004 elections, and that the current Parliament would get a "first reading" prior to that date. This would tend to solidify Parliament's position on REACH in its subsequent second and third readings. The EU Parliament tends to be more "green" than the EC, and would thus be likely to approve or even strengthen REACH. Final approval by the Council of Ministers from EU nations was expected in 2005. Individual nations would then have to incorporate REACH into their own national laws. It should be noted that the majority of EC's legislative proposals eventually become EU law.

The EU chemical industry is concentrated in four nations. Germany is the largest, accounting for 26% of EU production in 2000, followed by France (17%), the U.K. (14%), and Italy (12%). With the exception of France, output growth in the large EU producers remains less than the U.S. Small manufacturing enterprises, with less than 250 employees, account for 28% of production value in the EU chemicals industry. The aggregate European chemical industry remains competitive internationally, with the U.S. as its single biggest competitor.

1. PRINCIPLES

REACH recommended that the EU adopt an unprecedented complex of regulations for industrial chemicals. These were designed to "make a major contribution to achieve safe use of chemicals at a global level." EU Environment Commissioner Margot Wallström hailed these proposed regulations. "The new policy introduces a radical paradigm shift. It is high time to place the responsibility where it belongs, with industry."

While stressing these critical safety concerns, the REACH proposals were also designed to stimulate industrial innovation, particularly developing cost-effective safe substitute technologies and products. Another important objective was to encourage "the *substitution* of dangerous by less dangerous substances where suitable alternatives are available."

REACH proposed that the following generic classes of industrial chemicals should be regarded as of "Very High Concern" (VHC):

- Category 1 or 2 CMRs, which are known (Category 1) or very likely (Category 2) to induce such toxic effects in humans.
- Chemicals that can become widely disseminated in the environment, and which are **p**ersistent, **b**ioaccumulative, and **t**oxic (PBT), with particular reference to persistent organic pollutants (POPs).
- Chemicals that are **v**ery **p**ersistent and **v**ery **b**ioaccumulative (vPvB) in humans and wildlife, and for which toxicity data are still unavailable.

It should also be recognized that many of these chemicals are ingredients or contaminants in

pesticides, and in consumer products, including food, cosmetics and household products.

a. Registration

Industry is required to notify the ECB, which is responsible for the "Classification and Labeling of Dangerous Substances," of intent to produce or import new and existing chemicals in a Chemical Safety Report (CSR) dossier. The dossier includes the following information: data on the identity of each chemical; toxicological, and ecotoxicological properties of intended uses; estimated human and environmental exposures; production quantity; proposed classification and labeling; safety data sheet; preliminary risk assessment; and proposed risk management. This information is to be entered into a publicly available database to be managed by the ECB; industry is required to pay fees for each submission. Registration of basic information is required for the following:

- About 30,000 High Production Volume (HPV) chemicals manufactured or imported by any industry in excess of 1t/p.a. (annually): estimatedly, 80% of these would only require registration before 2013.
- "Article" type: finished articles classified as dangerous, or if dangerous substances are released from them in excess of 1t/p.a. (annually).
- Experimental or R&D chemicals produced by any company in amounts less than 1t/p.a.; waived for at least 5 years.

In an attempt to reduce registration costs, the EU encouraged industry to form consortia, and to share CSR data. REACH would require manufacturers and importers to pre-register their chemicals at least 18 months prior to the registration deadline. Companies that pre-register the same chemical can participate in a Substance Information Exchange Forum where they can share testing and related information, whose costs are estimated to range from €75,000 to €125,000 per chemical. REACH would also impose penalties to discourage "free riding" by companies refusing to pay their fair share of testing costs.

b. Evaluation

Testing of HPV chemicals is tiered on the basis of marketed volumes in excess of 1t/p.a., as follows:

- 1-10t: physicochemical, toxicological, and ecotoxicological data are required; testing should generally be limited to *in vitro* methods.
- 10-100t: "base-set" testing is required, on a "case by case basis," for chemicals suspected, for reasons including quantitative structure activity relationship (QSAR), to be persistent, bioaccumulative, toxic (PBT), and CMR.
- 100-1,000t: "Level 1" substance-tailored testing for long-term effects is required based on information including physicochemical properties, uses, and exposures.
- Over 1,000t: "Level 2" additional more comprehensive long-term testing is required.

Testing requirements for an estimated 5,000 chemicals exceeding a production volume of 100t are critical in view of the gross inadequacy of current test data on HPV chemicals. A 1999 review of about 2,500 HPV chemicals, based on the "International Uniform Chemical Information Database" (IUCLID), revealed that no data were available for 21%, less than required "base-set" data were available for 65%, and "base-set" data were available for only 14% (9). Moreover, a 1998 review revealed that internationally accepted "Screening Information Data-Sets" (SIDS) were available for only 8.5% of all U.S. HPV chemicals (10).

c. Authorization

Authorization will be granted for an estimated 1,400 VHC chemicals, including those produced in volumes below 100t/p.a., estimatedly 5% of registration chemicals. This will be granted subject to specific conditions and strict deadlines. The following categories of VHCs are specified:

- 850 chemicals currently classified as category 1 or 2 CMRs; about an additional 500 CMRs may be identified through future testing.
- Chemicals with persistent organic pollutant (POP) characteristics.
- Endocrine disruptive chemicals (EDCs) which have been associated with reproductive cancers, hormonal effects (including congenital disease and male infertility), and impaired immune and nervous system development, and also endocrine abnormalities in wildlife.

2. OBJECTIVES

- Reducing poorly recognized adverse public health and environmental impacts, and their poorly recognized major economic costs, particularly from avoidable exposures to toxic industrial chemicals.
- Reducing industry's concerns on costs from anticipated toxic tort litigation, on behalf of citizens and workers, and civil liability for environmental damage (11). However, these are of limited deterrence, as awards by EU courts are still lower than in the U.S.
- Reducing industry's liability from anticipated claims based on human rights jurisprudence (11).
- Reducing poorly recognized adverse environmental impacts, besides their poorly recognized externalized major economic costs, from avoidable contamination of air, water, food, and the workplace with VHC chemicals.
- Stimulating industry innovation: by encouraging "the substitution of dangerous by less dangerous substances where suitable alternatives are available."
- Increasing transparency: making industry responsible for "providing full information to the public—so creating pressure on industry to develop safe substances."

- Encouraging progressive industry and downstream users to further expand current safe product markets, and stimulate the development of new safe substitute products and markets.

3. ESTIMATED INDUSTRY COSTS

- Registration: €300M.
- Testing: 30,000 HPV chemicals: €2.1B
- Total: €2.4B.
- Administrative costs: approximately €0.4B; will be recovered on a fee-based system.

Spread over 11 years, these costs are approximately 0.05% of the EU chemical industry's €417B turnover in 2000. REACH also indicates that some of these costs may be passed on to downstream companies, presumably these costs would then be shared by the public. Furthermore, these costs are likely to be dwarfed by costs of poorly recognized public health and environmental impacts to which REACH makes the briefest reference. These include the "significantly increased ... incidence of testicular cancer in young men, and allergies over the last decades, for which the underlying reasons have not yet been identified." REACH also fails to make any reference to legal costs and human rights liabilities from failure to regulate the EU chemical industry (11).

4. TRANSPARENCY AND RIGHT-TO-KNOW

In principle, REACH recognizes the need for increasing transparency, avoidance of conflicts of interest in advisory committee members, and for providing full information to the public. "The public has a right to access to information about the chemicals to which they are exposed. This will enable them to make develop safer substitutes."

Nevertheless, REACH states that the EC "believes that industry . . . should mainly be responsible for providing information on health and environmental effects to consumers." REACH also assures industry that "commercially sensitive information will be suitably protected."

5. REACTIONS TO REACH

The principles of REACH have received strong support from E.U. and U.S. cancer prevention and public health scientists, and physicians. These include those represented by the Association Française pour la Recherche Thérapeutique Anti-Cancéreuse (ARTAC), and the Cancer Prevention Coalition (CPC), representing approximately 100 leading cancer prevention and public health scientists, and also representatives of NGOs and citizen activist groups. In the EU, these groups include: the European Environmental Bureau (EEB), a coalition of 146 NGOs, the World Wildlife Fund-U.K. (WWF-U.K.), Pesticide Action Network (PAN), and the European Trade Union Technical Bureau (TUTB). In the U.S., these groups include: the Science and Environmental Health Network, Physicians for Social Responsibility,

the Alliance for Safe Alternatives, the Lowell Center for Sustainable Production, the Environmental Health Fund, the Environmental Working Group, and the Natural Resources Defense Council.

A few industries have welcomed REACH. BP Chemicals-Europe greeted the five-year registration waiver for experimental substances as "good news." More broadly, Bayer AG emphasized that REACH would encourage innovation, by forcing companies to develop substitutes for hazardous chemicals.

However, the REACH proposals have met with overwhelming resistance from other European and American chemical industries and trade associations, including the European Chemical Industrial Council (CEFIC: 12), the American Chemistry Council (ACC: 13), and the American Chamber of Commerce to the EU. They claimed that REACH requirements would stifle innovation, result in major job losses, pose inflationary costs, disrupt global trade, and violate trade secrecy and World Trade Organization Rules (14).

At the root of these claims is a fundamental ideological opposition to the Precautionary Principle, as exemplified in REACH. This requires governments to base regulatory policies proactively on the probability, or reasonable possibility, of risk. However, the position of industry, supported by U.S. regulatory policy, is insistence that regulations should only be imposed retroactively in response to "credible evidence of unreasonable risk" of disease, death, or environmental degradation, and then only following a cost-benefit analysis (15).

In striking contrast to EU governments, which have maintained neutral positions, the Bush Administration has encouraged industry to take aggressive opposition to REACH (15-17). Secretary of State Colin Powell, in a March 2002 U.S. "Nonpaper on EU Chemical Policy," warned that the Precautionary Principle would result in "politically motivated bans" of U.S. chemical products (15), which account for over 20% of all U.S. exports (14). Dr. John Graham, Administrator of the U.S. Office of Information and Regulatory Affairs, and former Director of the industry-funded Harvard University Center for Risk Analysis, in a May 18, 2003 speech to EU regulators, stated that the Administration considers the Precautionary Principle "to be a mythical concept, perhaps like a unicorn" (16).

Confidential documents obtained under the U.S. Freedom of Information Act, have revealed that the U.S. State and Commerce Department, the Environmental Protection Agency, and Office of the U.S. Trade Representative, have formed an alliance with Dow Chemical to fight REACH (18,19). These tactics, however, may backfire. Senator Frank Lautenberg (D-NJ), with other influential Congressional democrats, is drafting a proposal to overhaul U.S. regulations to resemble the EU's proposed reforms (20, 21).

The mainstream industry opposition has been mobilized by the ACC and the CEFIC, each accounting for approximately 30% of the world's chemical production. The Trans-Atlantic Business Dialogue (22) has been established to coordinate industry opposition to REACH. A leaked ACC memo has revealed aggressive and well-funded plans to fight laws and regulations based on the Precautionary Principle (23).

ACC's public relations campaign is being handled by Nichols-Dezenhall, which has hired former FBI and CIA agents to create phony front groups, and spy on environmental activists, including digging through their trash in efforts to smear them.

These behind-the-scenes tactics are in striking contrast to industry's initiatives to sanitize its public image. The ACC has announced a "Reputation Initiative," advocating a "High Production Volume (HPV) Chemical Testing Program," and a "Long-Range Research Initiative on Testing Chemical Hazards" (24). Along similar lines, the Chemical Manufacturer's Association (CMA) has launched a "Responsible Care Campaign.—We are not asking the public to trust us. We are asking everyone to track us" (24).

In its May 2002 preliminary comments, CEFIC requested exemption of the following from REACH requirements; all chemicals which "are adequately controlled by other legislation;" R&D chemicals; "substances" marketed below 1t/p.a. per manufacturer; and polymers and their intermediates(12). The request for polymer exemption has been strongly reinforced by other industries, notably Hydro Polymers, which insisted that polymers, "including PVC present a low level of harm." This industry also insisted that it was unreasonable to be concerned about endocrine disruptive phthalates, in view of the EC's failure to take action against contamination of water with natural or contraceptive estrogens.

The first formalized critique of REACH was detailed by the ACC in July 10, 2003 (13): "REACH is impractical and too costly and should be replaced by a "risk-based approach;" REACH is trade restrictive and incompatible with WTO objectives, and international chemical regulations; the EU should instead rely on existing registration and risk management, rather than REACH; and the high costs of REACH would impose a negative impact on innovation and competitiveness of EU industry.

ACC's more specific criticisms include: the "duty of care" base set CSR data requirements are impractical and too costly, and should be replaced by tailored testing requirements, based on use and exposure patterns; polymers should be exempted from registration requirements in "view of the low risk to health and the environment;" the high priority regulatory requirements for VHC chemicals should only be authorized if warranted by "use and exposure patterns;" endocrine disruption is "a mode of action and not a health effect," and thus inappropriate for Authorization; and that Authorization would force industry to "develop and submit socio-economic substitution."

The opposition to REACH by EU and U.S. industry was so strong that the EU was forced to make substantial concessions. These were jointly developed by the Swedish Environment Commissioner Margot Wallström, and Enterprise Commissioner Erkki Liikanen. Key among these was the reduction from 30,000 to 10,000 HPV chemicals, for which comprehensive safety testing would be required, in spite of the minimal available test data on most of them. Among other major concessions was the exemption from requirements for data on reproductive toxicity, and environmental persistence of chemicals produced in amounts from

1-10t.

THE 2003 WEAKENED VERSION OF REACH

In May 2003, the EC issued its revised legislative proposals as a Staff Working Paper, which was finalized in October 2003 (25). These revisions reflect strong pressure by EU and US industries, and the US Administration. To a lesser extent, these proposals also reflect political and economic differences between EU member states. The Working Paper was adopted as the final basis for regulations in October 2003 (25).

1. PRINCIPLES

The stated objectives of the Staff Paper are similar to those of REACH. However, the latter requirements have been sharply reduced in response to heavy pressure to reduce the alleged high costs of regulation to industry. This is paralleled by the EC's limited recognition of the much higher, poorly quantifiable health and environmental costs of past and current failure to regulate, let alone future costs. This is also paralleled by inadequate recognition by industry of the increasing likelihood of toxic tort, and other legal and human rights liabilities.

Reflecting these perspectives, the revised REACH proposals have drastically curtailed their earlier objectives. This has been achieved by "lightening," waiving, or even exempting most registration and other requirements (Table 2).

a. Registration

Industry is exempt from any requirements to submit Chemical Safety Reports, and most other requirements are lightened or even waived.

- HPV chemicals manufactured or imported in amounts below 10t/p.a.: waived for at least 6 years, and then subject to review.
- Chemicals manufactured or imported in amounts below 1t/p.a.: exempted.
- Intermediates: unspecified "lighter requirements."
- R&D chemicals: exempted for up to 10 years.
- Polymers: exempted.
- "Articles": exempted, unless they contain a chemical classified as dangerous, and which can be released from the products.
- Imports: exempted, unless they contain chemicals classified as dangerous, and which can be released from the products.
- Downstream users: exempted.
- Transparency: breached by a "practical formula" provision for protecting confidential business information.

TABLE 2: SUMMARY COMPARISON OF REACH 2001 AND ITS 2003 VERSION

	REACH 2001	2003 VERSION
REGISTRATION		
Chemical safety reports	Required	Exempted
HPV chemicals ¹	>1t: Required	1-10t: Lightened
Polymers	Required	Exempted
Imports	Required	Exempted
Downstream users	Required	Exempted
Transparency	Required	Exempted (by "a practical formula")
EVALUATION		
HPV chemicals	30,000	10,000
AUTHORIZATION		
VHC chemicals ²	Required	May be waived ⁷
CMRs 1&2 ³	Required	May be waived ⁷
PBTs ⁴	Required	May be waived ⁷
vPvB ⁵	Required	May be waived ⁷
EDCs ⁶	Required	May be waived ⁷

¹High Production Volume

²Very High Concern

³Carcinogens, mutagens, reprotoxics

⁴Persistent, bioaccumulative, toxics

⁵very Persistent, very Bioaccumulative

⁶Endocrine disruptive chemicals

⁷On the basis of "socio-economic grounds," or claims that, risks can be "adequately controlled," or there is "no right to concern."

b. Evaluation

- CSR testing requirements for HPV chemicals: reduced from 30,000 to 10,000.
- CSRs for downstream users: replaced by "Safety Data Sheets."
- Chemicals manufactured or imported in "the sensitive 1-10t/p.a. range:" "lower test requirements."
- R&D chemicals: testing threshold increased from 10 kg-1t/p.a.

- Testing requirements for chemicals: waived if "unnecessary," or if "information can be obtained by other means," or "if profile of use does not require it."
- Polymers: exempted from any testing requirements.
- Intermediates: drastic reduction from any testing requirements.
- Downstream users: exempted from any testing requirements.
- For any amount of any chemical: CSRs could be waived by encouraging development of computer-based qualitative or quantitative structure activity relationships (Q)SARs that may "permit the prediction of . . . environmental or health effects without the need for further animal tests."

However, in spite of numerous studies on such short-term (Q)SAR tests over the past four decades, there is minimal evidence on their reliability and ability to predict synergistic interactions and complex metabolic processes. In sharp contrast, the validity of extrapolating carcinogenicity evidence from rodent tests to human risk has been overwhelmingly supported for decades by independent scientists, blue ribbon expert federal and non-federal committees, and by the World Health Organization's (WHO) International Agency for Research on Cancer (IARC). Additionally, positive evidence from numerous rodent tests has been confirmed epidemiologically, generally decades later (26). Of striking relevance is the December 2002 report of the International Consortium's Mouse Genome Project which reported that roughly 99% of mouse genes have a functional equivalent in the human genome, that their biological programming is amazingly similar, and that the mouse is thus an ideal laboratory animal for investigating the molecular basis of human disease (24, 26).

Furthermore, in view of industry's decades-long attempts, on a variety of spurious grounds, to challenge the validity and human relevance of rodent carcinogenicity data, it is unlikely that industry would accept any positive (Q)SAR data on carcinogenicity. It is equally likely that industry would claim negative (Q)SAR data as exculpatory.

c. Authorization

The Staff Paper offers industry the opportunity to avoid Authorization costs for VHC chemicals, either "on socio-economic grounds," by presenting a plan for "adequate control," and future R & D on safe substitutes to hazardous chemicals. These loopholes fail to reflect the current availability of a wide range of such cost-competitive substitutes.

d. Public Information

It is claimed that "the public at large will benefit from the information gathered because of REACH, as they will be better informed about potential risks from specific substances." Apart from this single reassuring sentence, there is no indication whatsoever as to how any such information will be made available

to the public and to industry workers (27). Furthermore, there is no evidence that the public and labor, and their NGO and other representatives, have been consulted in the development of the finalized 2003 proposals.

2. THE 2003 PROPOSALS UNDERESTIMATE THE BENEFITS OF REGULATION

Based on selected or unreferenced sources, the 2003 proposals understate the benefits of regulation. Examples include the following:

- 90% of the health benefits associated with chemicals are either related to historical exposures, will not be identified by REACH, or cannot be tackled.
- "The proportion of all diseases due to agro-industrial chemicals and chemical pollution from diffuse sources is between 0.6% and 2.5% in developed market economies" (28).
- "For occupational cancer in developed countries—there would be an equivalent of 4,500 lives saved per year due to REACH."

3. REACTIONS TO THE REVISED 2003 PROPOSALS

In contrast to their overwhelming support of REACH, the 2003 proposals have been strongly criticized by ARTAC, CPC, scientists from Technical Working Groups of the SCALE initiative, and a wide range of citizen and labor groups, and NGOs.

REACH SHOULD BE STRENGTHENED, NOT WEAKENED

The EC must be strongly commended for developing REACH. However, these proposals have been weakened by EC's capitulation to pressure by EU and U.S. industries, strongly reinforced by the U.S. Administration. These concessions are also responsive to exaggerated claims of the costs of REACH, which in fact are only 0.05% of the chemical industry's €417B turnover in 2000. In striking contrast, the 2003 Staff Paper fails to recognize the much higher public health and environmental costs of its drastically weakened regulations. Clearly, REACH should be strengthened, not weakened (Table 3).

1. EVALUATION

REACH's minimal requirement for *in vitro* test data for 1-10t/p.a. HPV chemicals is scientifically untenable. It ignores the highly questionable validity and relevance of such data, apart from concerns on carcinogenic and EDC potency.

More importantly, REACH focuses on the carcinogenic and other toxic effects of individual chemicals, particularly VHC, to the exclusion of well-documented evidence on additive and unpredictable synergistic interactions between individual carcinogens (26). Of additional concern is extensive evidence on the effects of lipophilic chemicals in increasing the percutaneous and inhalation absorption, and synergizing the toxicity of a wide range of individual chemicals, such as formaldehyde, styrene, and atrazine (29).

TABLE 3: HOW TO STRENGTHEN REACH

MANDATORY SUBSTITUTION OF VHC CHEMICALS

AUTHORIZATION to be denied if safe alternatives are available.

TRANSPARENCY: CITIZENS' RIGHT-TO-KNOW

- Independent audit of industry chemical safety dossiers prior to REGISTRATION.
- Independent audit of industry claims for waiving AUTHORIZATION of VHC chemicals, based on no "right to concern," or that risks can be "adequately controlled."
- Comprehensive information on air and water emissions of industries handling VHC chemicals.
- Comprehensive information of industrial contaminants in air, water, the workplace, and consumer products—food, cosmetics, and household products.
- Assurances that downstream users will be fully informed, other than by industry, of identity, volume, and dangers of registered and unregistered chemicals.
- All advisory committees should include representatives of independent expert stakeholders, and meetings should be open to the public; all committee members should fully disclose their conflicts of interest.

EVALUATION OF BENEFITS

- Estimated health benefits, €50B over 30 years, do not reflect the escalating incidence of non-smoking related cancers, nor early life exposures due to industrial chemicals.
- Environmental benefits should be estimated and recognized.
- Industry benefits from technological innovation stimulated by REACH should be estimated and recognized.

EVALUATION OF COSTS

- Independent audit of industry's claims of high costs of REACH, as the basis of aggressive industry opposition.

RECKLESS INDUSTRY PRACTICES ARE VIOLATIONS OF HUMAN RIGHTS, AND WHITE COLLAR CRIME

INCORPORATION OF THE 2003 EUROPEAN ENVIRONMENT AND HEALTH STRATEGY WORK PLAN (SCALE)

INCORPORATION OF THE 2004 EUROPEAN POLLUTANT EMISSION REGISTER

INCORPORATION OF THE 2004 ROTTERDAM CONVENTION ON PRIOR INFORMED CONSENT FOR IMPORT OF INDUSTRIAL CHEMICALS

- Prohibition of import of all HPV and VHC chemicals which have not been registered and evaluated under the terms of REACH.
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2. AUTHORIZATION

The proposed REACH ban or restriction of HPV chemicals is flawed by the exemption permitting their continued use, if industry claims that their risks can be "adequately controlled." This qualification is an open invitation to claims for exemption, based on definitional grounds.

For this reason, all claims for "adequate control" should be subject to mandatory evaluation by an independent advisory committee, appointed by the European Chemicals Bureau (ECB), and funded by the applicant industry. The composition of such a committee should reflect balanced representation of a wide range of qualified stakeholders, including independent scientific and technical experts, and NGO and labor representatives.

3. TOXICS USE REDUCTION

Industries manufacturing or processing HPV chemicals should be required to implement toxics use reduction programs. These should be modeled on the requirements of the Commonwealth of Massachusetts 1989 "Toxics Use Reduction Act," as a precedential legislative statement on the Precautionary Principle (30). The Act created the Massachusetts Toxics Use Reduction Program, focused on reducing the use of toxic chemicals, and the generation of hazardous wastes by improving and redesigning industrial products and processes.

Within 10 years of the Act's passage, its achievements included reducing the use of toxic chemicals by 40%, toxic wastes by 58%, and toxic emissions by 80%. Additionally, a cost benefit analysis revealed a savings of \$11.1 million to the 550 industries and companies involved. The program is ongoing, and has been recently expanded to incorporate toxics substitution (31).

The continued use by industry of VHC chemicals should be made subject to mandatory requirements by the ECB for routine monitoring for point source and fugitive air emissions, and water discharges. The continued use of these chemicals should also be subject to requirements for material balance studies in order to match outputs to inputs, and thus quantify environmental losses, and enable prompt process remediation.

In this connection, the EU industry has claimed that there have been major reductions in air and water emissions over recent years. However, these reductions have been largely offset by major increases in productivity (Table 4).

4. THE SUBSTITUTION PRINCIPLE

REACH states that an "important objective is to encourage the *substitution* of dangerous by less dangerous substances where suitable alternatives are available." However, REACH fails to mandate this principle as an obligate requirement for Authorization. Substitution is a critical basis for risk prevention, in contrast to

**TABLE 4: E.U. CHEMICAL INDUSTRY: RECENT CHANGES IN
EMISSIONS AND PRODUCTIVITY**

	Percentages
Atmospheric Emissions ¹ , 1990-2001	
Green house gases (e.g. nitrous oxide)	-50
Acidifying gases (e.g. sulfur dioxide)	-48
Ozone precursors (e.g. non-methane VOCs)	-38
Water Emissions ¹ , 1996-2000	
Chemical oxygen demand	-17
Nitrogen compounds	-25
Heavy metals	-43
Productivity ² , 1990-2001	+33

¹Based on industry data (12)

²Based on (25)

industry's continued emphasis on "risk management" (32). Recognition of this fundamental principle has been recently emphasized by the Swedish Government which explicitly stated that authorization of hazardous chemicals should be granted only if industry can demonstrate that safe substitutes are unavailable (33). Similarly, the U.K. Royal Commission has "recommended that the U.K. Government adopt substitution as a central objective of chemicals policy" (34).

Allowing for reasonable phase-in time, substitution should be a routine requirement for the Authorization of very high concern chemicals (VHC), particularly those that are persistent, bioaccumulative, and toxic (PBT). Exceptions to this requirement should be contingent on confirmation by the Chemical Bureau, in transparent decision making proceedings, that safe substitutes are neither available nor pending.

Over the last decade, an increasing number of progressive industries and retailers have made major advances in substitution for a very wide range of VHC chemicals, based on substantial developments in Green Chemistry, and Clean Production technologies (35,36).

Examples include:

- Substitution of the use of lead in soldering and electronic products by tin, silver, copper bismuth, and zinc. This has been implemented by industries including IBM, NEC, Phillips, Panasonic, Fujitso, Matsushito, and Hitachi.

- Substitution of PBDE flame retardants by internal metal framed casings, or polycarbonate resin retardants, particularly in printed wire circuit electronic boards. This has been implemented by industries including IBM, Motorola, Hewlett Packard, NEC, Apple, Great Lakes Chemicals, Sumitomo Dow, Matsushita, and Bayer, and by retailers including Marks & Spencers, and H & M.
- Substitution of alkylphenol ethoxylate (APE) surfactants by alcohol ethoxylates in textile and leather finishing treatments, water based paints, and cosmetics. This has been implemented by industries including Colgate-Palmolive, Procter & Gamble, and by major retailers including Boots.
- Substitution of chlorinated solvents by supercritical carbon dioxide in microelectronics, paints, paint coatings, manufacture of polymers, such as Teflon, and dry cleaning processes. This has been implemented by industries including Dow Chemical, DuPont, Micell Technologies, and Global Technologies.
- Substitution of agricultural, municipal, and domestic uses of synthetic pesticides by well-developed and cost effective Integrated Pest Management (IPM) techniques.

It should further be emphasized that the substitution principle will also avoid and solve the "current paralysis by analysis," inherent in REACH's requirements for comprehensive testing of HPV chemicals (32).

5. THE ECONOMIC BENEFITS OF REGULATION

REACH should be strengthened by explicit reference to the very high, and increasingly recognized public health and environmental costs of under-regulation.

A recent economic study has stressed that, "Caution can be costly, but indifference to serious risks can be disastrous. . . . Furthermore, the costs of mitigation often are far less than initially projected, because of induced technical changes; delaying mitigation can therefore increase costs" (37). Examples include estimates by the U.S. Environmental Protection Agency (EPA) of \$22 trillion net human health benefits of the 1970 Clean Air Act over a 20-year period (38), and the estimated 300,000 deaths averted by the control of chlorofluorocarbons (39).

Such major benefits to the EU are in striking contrast to exaggerated industry claims of the high costs of REACH's proposals.

6. THE RIGHT-TO-KNOW

REACH should be strengthened by emphasis that the right-to-know is an inalienable democratic principle, with the exception of sensitive national security concerns. This right clearly extends to information on avoidable risks of disease and death, and environmental contamination, due to industry practices. As such, these rights override claims of trade secrecy and confidentiality. It should, however, be recognized that the right-to-know in the EU, besides other nations, is more honored in the breach than the

observance. REACH should explicitly acknowledge this right, and detail the mechanism for its widest implementation.

a. Public Exposure to HPV Chemicals

Recognizing these rights, REACH should mandate that all industries manufacturing or processing HPV, particularly VHC, chemicals develop routine automated monitoring of point source, and fugitive toxic emissions to air, and of discharges to water. Such monitoring data should be made contemporaneously available to the public, and the ECB. Requirements for atmospheric monitoring should also be extended to municipal solid waste incinerators, in view of their emissions of high levels of dioxins and furans from the combustion of plastics, chlorinated organic chemicals, and other downstream products based on HPV chemicals, and household trash (40,41).

The public and farmers should also be explicitly warned of cancer risks from uses of the common pesticides, such as phenoxyacetic acid and chlorophenols. Since their 1978 ban in Sweden, the incidence of non-Hodgkin's lymphoma, which had been increasing in previous decades, has subsequently decreased sharply. In sharp contrast, the incidence of this cancer in France and the U.S. has approximately doubled over the last two decades (24, 43).

The public's right-to-know should also extend to consumer products, the ultimate downstream source of public exposure to toxic industrial chemicals, particularly CMRs. It should be stressed that food, household products, and cosmetics and toiletries contain a wide range of undisclosed CMRs. Notable are: carcinogenic pesticides in household products; carcinogenic pesticide residues in grains, vegetables and fruits; carcinogenic ingredients and contaminants in cosmetics; and EDC phthalates, and other ingredients in cosmetics. These should be clearly labeled with explicit "red flag" warnings, and the name and concentration of each CMR in each product. The ECB should consolidate all such data, publish them on a regular basis, and make them contemporaneously available, in a computerized Toxic Release Inventory database, to local communities nationwide.

b. Occupational Exposure to HPV Chemicals

Workers are at the highest risk of high level exposure to HPV, particularly VHC, chemicals. Industry must recognize workers' right-to-know of information on all such life-threatening dangers. These include specific information on the chemical and common name of each carcinogen, and carcinogenic process. Additionally, each industry must provide workers and their representatives with specific information on precautions taken to avoid inhalation and skin exposures. These include: the use of closed system technologies; exhaust ventilation; continuing and sensitive automated air monitoring; surface monitoring; and personal respiratory and skin protection. All such information must be made contemporaneously available to workers, and their representatives.

c. Body Burdens of HPV Chemicals

Considering the wide range of exposure of the public to HPV chemicals, it is not surprising that many have been identified, particularly in the U.S., as "body burden" contaminants in fat and blood of the general population. This information would be likely to mobilize large scale national support for strong regulatory action to protect against such unarguable evidence of reckless industry practices.

Over the last three decades, the Environmental Protection Agency (EPA), and the Centers for Disease Control and Prevention (CDC) have issued a series of reports on body burdens of persistent organic pollutants (POPs), including DDT, aldrin, dieldrin, chlordane, heptachlor, and their metabolites. These reports include:

- National Human and Nutrition Examination Surveys (NHANES) 1970-1998. This identified high concentrations of 8 POPs in 4,600 serum samples from the general population; 99% of these were contaminated with average DDT levels of 14 ppb.
- National Human Milk Study (NHMS), 1977-1983. This was based on analyses of 1,850 breast milk samples; 55% were found to be contaminated with average heptachlor epoxide levels of 77 ppb.
- CDC's January 2003 National Report on Human Exposure to Environmental Chemicals. This survey identified 116 contaminants in the serum and urine of over 2,000 volunteers, selected as representative of the U.S. population from 1999-2000. These contaminants were grouped as follows: dioxins and furans; PCBs; polycyclic aromatic hydrocarbons (PAHs); pesticides—organochlorine (OCP), organophosphate (OPP), carbamate, and herbicides; phthalates; heavy metals; and phytoestrogenic EDCs.

Not surprisingly, similar results have been reported from the EU. In their November 2003 National Biomonitoring Survey, the WWF-UK reported on analyses of serum from 155 UK volunteers for 78 industrial chemicals. These belong to three major groups: OCPs, including DDT and lindane; polychlorinated biphenyls (PCB); and polybrominated diphenyl ether (PBDE) flame retardants. Every single volunteer was found to be contaminated with chemicals from each group. The median to maximum concentration ranges were as follows: total OCPs, 130-2,700 ppb; total PCBs, 17-670 ppb; and PBDEs, 6-420 ppb. As stressed in the report, all contaminants in each group are very persistent and very bioaccumulative (vPvB); many are also CMRs.

EU's Environment Commissioner Margot Wallström also participated in this survey. The median concentrations of contaminants in her serum were as follows: PCBs, 166 ppb; OCPs, 133 ppb; DDT, 103 ppb; HCH (hexachlorocyclohexane), 15 ppb; and PBDEs, 6 ppb.

d. Responsibility of REACH

REACH should stress that only limited information is currently available to the public on avoidable environmental contaminants, with multiple HPV chemicals, and of their heavy body burdens with these contaminants. This would encourage national support for strengthening REACH, and also ensure public demand for its right-to-know of all such information.

e. The European Pollutant Emission Register

A recent landmark development in citizens' right-to-know is the EC's February 23, 2004 launch of a European Pollutant Emission Register (EPER). This public register is required to report about 90% of point source emissions to air and water by the largest and most polluting industrial facilities. These include: industries manufacturing chemicals, metals, ceramics, cement, and leather; oil refineries, power stations, and waste disposal plants; and intensive livestock rearing facilities. Such information is intended to stimulate industry to reduce pollutant emissions. EPER contains a wealth of data on pollutant emissions, readily available to the public at www.eper.cec.eu.int.

In protest, CEFIC claims that this register presents threats to industrial confidentiality and competition.

6. TRANSPARENCY

REACH is flawed by giving industry responsibility for transparency. REACH goes even further by breaching transparency with an unqualified provision ensuring that "commercially sensitive information will be suitably protected." Furthermore, REACH fails to recognize that regulatory decisions are generally based on recommendations by national scientific institutes and expert advisory committees. Their expertise, independence, integrity, and accountability are thus of critical concern, as is the transparency of their deliberations.

The composition of advisory committees should reflect balanced representation of qualified stakeholders, particularly scientists, and technical representatives of citizen groups, NGO's, and labor. Transparency of such proceedings should be further ensured by providing advanced public notice on scheduled meetings, which should be open to the public.

The EC has recently implemented a new policy of openness, by requiring declarations of interest by advisory committee members (44). The EC has claimed that these members act independently, make declarations of interest, and declare conflicts of interest at each meeting. Even if that were the case, such information has never been open to public scrutiny. Moreover, the EC maintains that contacts between committee members and commercial organizations are "part of normal and professional life," and should not be treated as "undesirable" (44).

The overdue need to avoid conflicts of interest is exemplified by clear evidence of corporate influence in the IARC, WHO's designated cancer research institute. IARC grades industrial and other chemicals for their carcinogenicity, also evaluating evidence for hormonal (EDC), and genetic toxicity. A letter co-signed by 30 prominent independent scientists has charged that, for nearly two decades, IARC has downgraded the carcinogenicity of a wide range of industrial carcinogens (45); this information has been recently detailed by a previous IARC director, a well-recognized international authority on chemical carcinogens (46). Such downgrading has exculpated some major carcinogenic chemicals from REACH's regulatory requirements (Table 5).

TABLE 5: DOWNGRADING OF CARCINOGENICITY RATINGS BY IARC

Carcinogen	Use	Year	Carcinogenicity Rating*
Saccharin	Artificial sweetener	1987	2B
		1999	3
Amitrole	Herbicide	1986	2A
		1987	2B
Atrazine	Herbicide	1991	2B
		1999	3
1,3-Butadiene	Plastics, synthetic rubber	1986	1
		1988	2A
Di(2-ethylhexyl) phthalate	Plasticizer	1987	2B
		2000	3
Glasswool (fiberglass)	Insulation	1988	2B
		2002	3
Ethylene thiourea	Vulcanization of rubber, and contaminant in EBDC fungicides	1987	2B
		2000	3

**Group 1, known; Group 2A, probable; Group 2B, possible; Group 3, not classifiable.*

Furthermore, there is evidence that IARC has not only invited industry representatives and consultants to its meetings, but has even paid their expenses (44). Additionally, numerous industry employees and consultants have attended IARC meetings as "observers," to the exclusion of independent experts.

Even more flagrant conflicts of interest are inherent in the recent recommendations of the ECB's Commission Working Group of industry consultants, which would drastically alter the criteria of IARC's categorization of carcinogens, besides also trivializing evidence on mutagens and reproductive toxins (47). These recommendations would virtually ensure that all carcinogens identified by standard testing procedures would be downgraded to IARC Group 3, and be exculpated from REACH's regulatory requirements on the following grounds:

"Appearance of tumors especially at high dose levels, only in particular organs of certain species known to be susceptible to a high spontaneous tumor formation; appearance of tumors, only at the site of application, in very sensitive test systems, if the particular target is not relevant to man; lack of genotoxicity in short term tests *in vivo* and *in vitro*; existence of a secondary mechanism of action with the implication of a practical threshold above a certain dose level; existence of a species-specific mechanism of tumor formation irrelevant to man."

The Commission Working Group has detailed these proposals, particularly those based on "policy considerations." However, these proposals have not been included in Directive 67/548/EC amendments, relating to REACH's regulation of CMRs.

It may be noted that a leading Working Group consultant is the geneticist Bruce Ames. Ames has been discredited for his insistence that there is no evidence for the increased incidence of cancer in the U.K. and U.S. other than due to tobacco, (and) for his dismissal of any risks from residues of carcinogenic pesticides in food (48).

There is also substantial evidence of major conflicts of interest in other WHO advisory groups, particularly those with responsibility for safety of consumer products, notably meat and milk. These groups include the Food and Agricultural Organization (FAO), and the Codex Alimentarius (FAO/CODEX). Examination of these groups "reflect minimal expertise in public health, high representation of United States Department of Agriculture (USDA) and Food and Drug Administration (FDA) officials, and industry consultants, and reliance on unpublished industry information" (49).

It should also be recognized that recommendations of advisory committees are ostensibly based scientific research reports. However, "there is growing evidence of conflicts of interest in private research submitted for regulation. For example, there are reports of a 'funding effect,' with sponsorship associated with favorable findings. There are also accounts of improper sponsor control over the design and reporting of results, and sponsor suppression or termination of research showing adverse effects" (50). For these reasons, personal and institutional requirements for transparency, and disclosure of conflicts of interest should be extended to published research, whether federally or privately funded.

Even more serious conflicts of interest are well recognized in regulatory policies of the U.S. Administration. A February 19, 2004 Knight Ridder newspapers article reported that an open letter from "more than 60 scientists, including 20 Nobel laureates and several science advisors to Republican presidents . . . accused the Bush Administration of suppressing, distorting or manipulating the work done by scientists at federal agencies . . . and (establishing) political litmus tests for scientific advisory boards."

7. "WHITE COLLAR" INDUSTRY CRIME

White collar crime is generally defined as crimes of economic motivation with adverse economic consequences. It has also been defined as crimes of economic motivation with adverse public health consequences, including cancer and other preventable disease, homicide, and environmental contamination. Examples of such crimes, with specific reference to the chemical industry, have been detailed in 1979 Congressional testimony as follows (51):

a. Knowing Acts of Nondisclosure

- Suppression of carcinogenicity and other toxicity data on vinyl chloride by vinyl chloride/polyvinylchloride industries, and by the Chemical Manufacturers Association.
- Suppression of carcinogenicity data on bischloromethylether by Rohm & Haas.
- Suppression of carcinogenicity data on the pesticide kepone by Allied Chemical.
- Suppression of mutagenicity data on benzene by Dow Chemical.

b. Reckless Acts

- Gross exaggeration by Arthur D. Little, Inc. (under contract to the Society of the Plastics Industry, Inc.), and by Foster D. Snell of data on the economic impact of compliance with a proposed occupational standard for vinyl chloride.
- Marketing of acrylonitrile plastic Coke bottles by Monsanto prior to its carcinogenicity testing.
- Falsification of test data on the drug aldactone, and the artificial sweetener aspartame by Hazleton Laboratories, under contract to G.D. Searle.
- Destruction of epidemiological data on occupational carcinogens by Dow and DuPont.
- Destruction of test data on drugs, food additives, pesticides, and industrial chemicals by Industrial Biotest Laboratories, a subsidiary of Nalco Chemical (under sub-contract to the Chemical Industry Institute of Toxicology).

It was recommended that responsibility for such crimes should be primarily directed to corporate directors and managers, and extended to other "knowing parties," including plant physicians and industrial hygienists, and outside consulting companies and scientists (50). As an important incentive to "disclosure," it was also recommended that any "whistle blowing" worker or other personnel who reported "serious" dangers, should be protected from retaliation or dismissal.

Recent disasters in the EU have resulted in renewed interest in white collar public health crime. In November, 2001, criminal charges were filed against managers of Celtica, an Italian petrochemical company plant in Brindisi (52). About 70 current managers of the plant, and former owners, including Montedison, Enichem and Evc, have been accused of environmental disaster, and mass manslaughter for the leukemia deaths of 14 workers, and the sickness of a further 83 workers as a result of exposure to vinyl chloride, and other toxic chemicals. While the first cases of leukemia were reported 23 years ago, investigation was delayed until prompted by a worker who has since died of cancer. The plant was closed by the police in November 2000.

Apart from criminal sanctions, the increasing likelihood of toxic tort and environmental litigation is likely to act as a growing deterrent to reckless industry practices. Consideration should also be given to the feasibility of obtaining redress from the European Court of Human Rights (53). Furthermore, personal rights to effective judicial remedy have long been established by the European Convention for Protection of Human Rights and Fundamental Freedom (54). These issues are also within the jurisdiction of the European Court of Human Rights at Strasburg. It should further be noted that various networks of environmental enforcement agencies have been recently established, including The European Network on the Implementation and Enforcement of Environmental Law. Of related interest is the non-profit Geneva and Washington, D.C. Center for International Environmental Law (CIEL), which is focused on global environmental concerns.

8. CANCER DUE TO INDUSTRIAL CARCINOGENS

REACH stressed the need for regulating HPV industrial carcinogens. However, explicit reference should be made to their role as major avoidable causes of cancer, as a poorly recognized result of inadequate regulation (26). Cancer is now a leading cause of disease and death in France and the U.S. (Table 6), now striking nearly one in two men and more than one in three women in their lifetimes.

TABLE 6: CANCER CASES AND DEATHS IN 2001

	FRANCE		U.S.	
	NUMBER CASES	% POPULATION*	NUMBER CASES	% POPULATION**
Male	161,000	0.26	643,000	0.22
Female	117,200	0.19	625,000	0.21
TOTAL	278,200	0.46	1,268,000	0.43
	NUMBER DEATHS	% POPULATION*	NUMBER DEATHS	% POPULATION**
Male	92,300	0.15	286,000	0.10
Female	57,700	0.10	267,000	0.09
TOTAL	150,000	0.25	553,000	0.19

*As of January 1, 2001. Pison, Gilles. *Population & Societes*. No. 366, March 2001. **U.S. Census Bureau.

Over recent decades, and contrary to public perception, the overall incidence of cancer in France and the U.S. has escalated to epidemic proportions (Table 7). This hardly justified the July 28, 2003 British Broadcasting Corporation Headline article, "Europe Winning Cancer Battle."

TABLE 7: PERCENTAGE CHANGES IN AGE STANDARDIZED CANCER INCIDENCE RATES

	<u>FRANCE, 1980-2000*</u>	<u>U.S., 1975-2000**</u>
Prostate	198	88
Malignant melanoma	171	124
Thyroid	149	54
Non-Hodgkin's lymphoma	103	71
Breast		
Overall	60	29
Pre-menopausal		6
Post-menopausal		37
Brain	57	14
Multiple myeloma	55	12
Testis	46	54
Acute leukemia	36	15 (myeloid)
Childhood (0-14)		
Overall	-	31
Acute lymphocytic leukemia	-	59
Brain	-	48
Kidney	-	43
Bone	-	20
<hr style="border-top: 1px dashed black;"/>		
Lung		
Overall	19	19
Male	10	-11
Female	132	103
All sites		
Overall	28	18
Male	27	20
Female	31	13

*Based on Remontet, L., et al. (43)

**National Cancer Institute. (55)

Over recent decades, the overall incidence of cancer, based on age-adjusted rates in the EU and U.S. has escalated to epidemic proportions. It should be emphasized that the major increases are accounted for by a wide range of predominantly non-smoking related cancers (Table 7). It should further be stressed that these increases, and to a lesser extent for non-hormonal cancers, are related to a wide range of carcinogenic environmental exposures.

It should further be emphasized that the virtually exclusionary fixation of EU and U.S. cancer institutions and governments on smoking and other lifestyle factors, as the predominant cause of cancer, remain based on undocumented 1981 "guesstimates" by Sir Richard Doll (Table 8). However, faced with mounting evidence and revelations of his major conflicts of interest as an undisclosed industry consultant, Doll has recently recanted and admitted the major importance of non-smoking causes of cancer. Notable among these are childhood cancers, for which lifestyle factors cannot be attributed, which have clearly been related to environmental exposures (Table 9).

a. Regional Cancer Clusters

Cancer clusters in regions adjacent to chemical industry plants and hazardous waste sites have long been recognized in the U.S. (26). Examples include: Salem County, New Jersey, with the highest national incidence of bladder cancers in men and women; Love Canal, Niagara Falls, New York, with an excess of leukemia, breast cancer and birth defects; and childhood leukemia in Woburn, Massachusetts, and in Sellafeld in the U.K. Such regional variations in cancer incidence prompted the National Cancer Institute to publish "cancer maps" showing clusters of excessive cancer rates in regions of heavy industrialization, and concentrations of chemical plants (56).

Similar clusters have been recently recognized in Italy. Citing WHO data, the environmental group Legambiente reported that cancer rates in industrial areas of Brindisi are a record of 48% higher than the regional average, and the highest in any other areas of Italy (57). Regional excesses in other highly industrialized areas and cities include: 46% in Crotona; 22% in Taranto; and 21% in Massa Carrara. It has been estimated that as many as 11 million Italians are at increased risk from such exposures.

b. Community Cancer Clusters Related to Municipal Solid Waste (MSW) Incinerators

Since 1997, yearly measurements of dioxin and furan emissions from MSW incinerators processing over six million tons of wastes hourly have become compulsory nationwide; high dioxin emissions were identified in 15 of 71 such incinerators. Reflecting these considerations, the authors stressed that the absence of a nationwide cancer registry precludes systematic analysis of cancer incidence and clusters around highly polluting MSW incinerators (58). Nevertheless, highly significant clusters of soft tissue sarcoma and non-Hodgkin's lymphoma have been reported from 1980 to 1995 among men and women living in the vicinity of

TABLE 8: SIR RICHARD DOLL'S TRACK RECORD ON PREVENTION

1950-1970: MAJOR CONTRIBUTIONS TO CANCER PREVENTION*

- Precedential research on smoking, nickel, gas production tars, asbestos, and radioactivity as causes of cancer.
- Warning that an "immense" number of substances were known to cause cancer.
- Warning that cancer prevention is a better strategy than cure.

1970-2001: UNDISCLOSED INDUSTRY CONSULTING

- 1976: Claimed that it was "unethical" not to treat drinking water with fluoridated industrial wastes.
- 1981: Undocumented claims ("guesstimates") that lifestyle factors are responsible for 95% of cancer mortality, and that only 5% are due to "pollution" and occupation.
- 1982: As a longstanding consultant to Turner & Newall, the leading U.K. asbestos industry, he reassured its workers that low level asbestos exposure was safe, and also refused to testify on behalf of dying workers or their bereaved families in litigation against the industry.
- 1983: As a consultant to General Motors, he denied that exposure to lead from leaded petroleum was hazardous to children.
- 1985: Supported Monsanto in trivializing cancer risks of dioxin and denying claims of compensation by Australian veterans exposed to Agent Orange in the Vietnam War.
- 1987: Dismissed evidence of excess rates of leukemia in children living near U.K. nuclear power plants.
- 1998: Claimed that excess mortality from leukemia and multiple myeloma in servicemen exposed to atom bomb test radiation was "a statistical quirk."
- 1998: On behalf of the U.S. chemical industry, he denied evidence relating occupational exposure to vinyl chloride and brain cancer.
- 2000: Admitted to "charitable donations" from Dow Chemical, "in recognition of all the work I had done for them."

2002: RETRACTION

- Admitted that most cancers, other than smoking, and hormones, "are induced by exposure to chemicals, often environmental."

*Ref 24 (Appendix 6)

TABLE 9: ENVIRONMENTAL RISK FACTORS FOR CHILDHOOD CANCER

- Industrial pollutants in drinking water.
 - Exposure to pesticides from urban spraying, and uses in schools, homes, gardens, and pet flea collars.
 - Contamination of fruits and vegetables, particularly in baby foods, with carcinogenic pesticides.
 - Exposures to wood playground sets treated with chromated copper arsenic.
 - Maternal and paternal pre-conception exposure to occupational carcinogens.
 - Proximity of residence to nuclear energy plants.
-

the Besancon (MSW) incinerator (59). Based on these results, local authorities have upgraded the combustion chamber of the MSW, and planned the construction of a modernized facility.

A case-control study confirmed the high risk of non-Hodgkin's lymphoma in the highest exposure zone surrounding the Besancon MSW. The authors stressed that emissions from MSW incinerators are one of the major environmental sources of dioxins, and casually belated to non-Hodgkin's lymphoma and other health risks (59).

c. Community Cancer Clusters Related to Nuclear Plants

Nuclear plants represent another major source of exposure to industrial carcinogens. However, they are regulated by the Directorate-General Environment (60), rather than by REACH.

A case control study has demonstrated a statistically significant increased incidence of leukemia in people under the age of 25 living in the vicinity of La Hague, one of the world's largest nuclear reprocessing plants. This was attributed to routine atmospheric emissions of particulate radionuclides, environmental marine contamination, the use of local beaches, and consumption of local fish (61). The excess incidence of childhood leukemia in the Nord Contentin region of France, where the La Hague reprocessing and other nuclear installations are located, has been independently confirmed (62); excess incidences of childhood leukemia have also been reported in the vicinity of the Sellafield reprocessing plant (63). These findings are consistent with the excess incidences of childhood leukemia in proximity to U.S. nuclear power plants (66). Further supportive is evidence of high levels of Strontium-90 in baby teeth of children living near U.S. nuclear plants (64).

In striking contrast, a well-designed investigation of people age 0 to 64 years in some 500 communes near 13 main French nuclear plants reported no excess cancer mortality (65). The authors, however, emphasized that their reliance on mortality, rather than incidence, data was due to the absence of a national cancer registry, and that local cancer registries did not include the area studied. "The availability of

incidence data would represent a substantial increase in power, particularly when studying cancers of the thyroid and breast, Hodgkin's disease, and childhood leukemia, for which survival is fairly good."

The French government has recognized risks of thyroid cancer in people living near its 19 nuclear power plants, and supplied them with stable iodine tablets as a precaution against the accidental release of iodine isotopes (66). This seems prudent in view of the major increase in the incidence of thyroid cancer in men and women from 1975 to 1995, which cannot be associated with the Chernobyl nuclear accident (67). Major excesses in the incidence of thyroid cancer have also been reported in the U.S following exposure to I-131 from radioactive fallout following atom bomb tests in Nevada in the late 1950's (26).

Apart from jurisdictional considerations, it should be recognized that there is a clear relation between exposure to radiation and chemical carcinogenesis. Exposure to radionuclides is known to depress the immune response, and thus enhance susceptibility to chemical carcinogens (68). Illustratively, radiation has been shown to synergize the carcinogenic effects of diethylstilbestrol in the breast (69).

d. Occupational Cancer

Specific provisions of the French Labor Code on the prevention of occupational cancer, based on a 1990 European Directive (70), apply to some chemicals, products and processes defined as human carcinogens (IARC category 1), and probable human carcinogens (IARC category 2). Workers developing cancer following exposure to these carcinogens, and carcinogenic processes (such as the manufacture of auramine, isopropyl alcohol, and roasting of cupro-nickel mattes) should be entitled to compensation.

It should, however, be emphasized that there has been only minimal priority and concern for occupational cancer. Most critical is the virtually exclusive responsibility of industry for all aspects of occupational health and safety, including compensation (through social security), with inherent major conflicts of interest. Not surprisingly, more and more workers are now suing their current employers or former employers to increase compensation or to obtain any compensation.

Related considerations include: the under-reporting of occupational cancer by poorly informed workers, and physicians without occupational expertise, particularly pneumologists (71, 72), and that most cancers are diagnosed after retirement, when their occupational causation tends to be unrecognized (71-74). Entitlements to compensation are still highly limited, and only extend to a few malignancies: lung, nasosinus, bladder, liver and skin cancers, leukemia, mesotheliomas, and osteogenic sarcomas. These restrictions also exclude other cancers for which there is valid evidence of occupational causation, such as brain cancer in farmers and vineyard workers exposed to pesticides (75), and non-Hodgkin's lymphoma in workers exposed to benzene, and agrichemicals (76). Moreover, compensation is restricted to male workers in some sectors, and excludes self-employed workers (including farmers, and agricultural workers).

Based on highly conservative and undocumented estimates that occupation is responsible for only 4% of cancer mortality (77), the number of compensable cases in France in 1999 should have been approximately 7,000 (71). However, the 4% estimate was based on just a guess by a prominent U.K. epidemiologist, an undisclosed industry consultant (Table 8) and contrary to prior confidential industry estimates of over 20% (74). Nevertheless, less than 1,000 male workers received compensation in 2001 (72).

In 1998, the Ministry of Health created a new public agency, the Institut de Veille Sanitaire (InVS), with a Health & Work Department (HWD) headed by an occupational physician and epidemiologist. Based on prevalence data from other appropriately matched nations, InVS estimated that the number of annually compensable occupational cancers is much higher than previously recognized, and about 8,500 (74). It should be further emphasized that, apart from mesotheliomas, lung cancer, following exposures to eight carcinogens and carcinogenic processes, accounted for over 50% of these cancers (74).

Furthermore, a recent authoritative report on occupational cancer in males, based on a wide range of cancers and carcinogens, estimated that the impact is substantially higher than previously recognized (73), with 20,000 annual cases and 13,000 deaths corresponding to incidences of 12% and 14%, respectively (Table 10). Of additional, but largely unrecognized, concern is the fact that some 20 U.S. and international studies have clearly incriminated parental occupational exposures to carcinogens as major causes of childhood cancer (26,48).

TABLE 10: COMPENSABLE OCCUPATIONAL CANCERS IN FRENCH MALES

1999 Estimates ¹	7,000
2001 Estimated compensated cases ²	<1,000
2002 Estimates ²	8,500
2003 Estimates ³	20,000

¹Aubrun, et al. 1999 (71)

²InVS, 2002 (74)

³Goldberg, 2003 (73)

Responsibility for ensuring the health and safety of workers involved in the manufacture and processing of carcinogenic, and other VHC, chemicals should be removed from industry and transferred to a responsible government agency. This should be staffed by highly qualified industrial hygienists and occupational physicians, and supervised by InVS, or a designated agency in close collaboration with InVS.

Additionally, health and safety and other labor representatives should actively participate in corporate governance. Under a 1976 German "Mitbestimmung" co-determination law, industries with over 2,000 workers are required to allocate labor half of the seats on supervisory boards, whose key decisions must be endorsed by top management. Reaffirmation of this two-tier system of corporate governance was urged by the DGB, Germany's national trade union federation, at a recent conference in Berlin (78). It should be further noted that a 2002 study by the Cologne-based Max Planck Institute for the Study of Societies concluded that co-determination had not hindered industry interests, restructuring, and globalization.

Of particular interest is President Chirac's March 2003 speech, in which he stressed the need to "strengthen the fight against cancers of occupational origin" (79).

9. PRIOR INFORMED CONSENT

On February 23, 2004, the Rotterdam Convention on Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade became international law; the Convention established the principle that the import of any industrial chemical be subject to PIC. Sixty State Parties, including the U.S., have signed the Convention, although the U.S. has not ratified it. Clearly, REACH should stipulate that the import of all VHC chemicals, and HPV chemicals which have not been Registered and Evaluated, be prohibited under the terms of PIC.

The PIC requirement would act as a powerful and overdue deterrent to the import of hazardous chemicals and products from Third World countries where environmental and occupational regulatory controls are minimal.

10. SCALE: THE EUROPEAN ENVIRONMENT AND HEALTH AND STRATEGY PLAN

In October 2003, following Regional Conferences in Brussels, Rome, and Warsaw, EU Environment Commissioner Wallström launched "The European Environment and Health Strategy Work Plan." Known as SCALE, this initiative, which is independent of REACH, is based on Scientific evidence, focused on Children, enhanced Awareness, Legal and political remedies, and dynamic Evaluation of progress.

It must be stressed that SCALE is politically unrelated to REACH. However, it strengthens REACH conceptually by stressing the critical importance of early life sensitivity to industrial chemicals.

SCALE has established three Technical Working Groups, focused on the following priorities:

1. Indicators and Priority Diseases: environment and health indicators; respiratory and neurodevelopment diseases; childhood cancer.
2. Integrated Monitoring of Children: pilot studies on dioxins, PCBs, heavy metals, and EDCs.
3. Research Needs.

While such research is obviously important, it should, however, be stressed that there is substantial evidence of the increasing prevalence of a wide range childhood diseases (80-83). There is also substantial

evidence of their known, or suspected, exposures to HPV chemicals and other environmental contaminants, especially during *in utero* and early life exposures. These include:

- Neurodevelopment disorders, including autism, attention deficit disorders, dyslexia, and mental retardation. These have been linked to neurotoxicants, including lead, mercury, and POPs, particularly PCBs.
- Hormonal disorders, including cryptorchidism, hypospadias, altered sex ratios at birth, sperm abnormalities, and premature puberty. These have been linked to EDCs, particularly POPs—PCBs, polybrominated biphenyls, and furans.
- Respiratory diseases, including asthma and allergies. These have been linked to ambient and indoor air pollutants, including fine particulates, diesel exhaust, and ozone.
- Cancer. While there is clear evidence of the sharply escalating incidence of a wide range of childhood cancers over recent decades in the U.S., there are no such comparable data in the E.U. (Table 7). Moreover, these have been linked to a wide range of environmental causes, including proximity of residence to nuclear energy plants, exposures to pesticides from urban spraying and uses in schools, particularly wood playground sets treated with chromated copper arsenate preservatives, industrial pollutants in drinking water, and maternal and paternal exposures (pre-conception and post-conception) to occupational carcinogens (Table 9).

It should be further stressed that *in utero* and early life exposures are significant determinants of reproductive abnormalities and other disease, including cancer, manifesting in adult life. The relation between treating pregnant women with DES and the rare vaginal cancers in their post-pubertal daughters, besides urogenital abnormalities in their adult sons, has been well recognized for over three decades (48). Even more relevant is recent evidence that testicular cancer, whose incidence rates in France and the U.S. have increased by over 40% in recent decades (Table 7), can be initiated during fetal life following exposure to EDCs (84). Blood levels of a wide range of OPPs, including chlordanes, PCBs, and hexachlorobenzene, were shown to be 3-4 times higher in mothers of men diagnosed with testicular cancer than in matched controls.

In addition to early life exposures and childhood disease, SCALE should direct highest priority to the overwhelming discrepancies between child health in Western and Eastern Europe. Illustratively, infant mortality rates in Western Europe are in the range of 3-6/100,000, while those in Eastern Europe range up to 17/100,000, reaching as high as 37/100,000 in Turkey (85).

Based on these widely ranging concerns, SCALE has developed an Action Plan with defined goals and actions for the period 2004-2010. This Action Plan will be the EC's major contribution to the Fourth

Ministerial Conference on Environment and Health, convened by the WHO's Regional Ministerial Conference, in Budapest in June 2004.

It should, however, be recognized that more than adequate scientific data are currently available to implement SCALE's objectives. In fact, emphasis on further research needs could be counterproductive, and exploited by industry for continued regulatory inaction. Clearly, the objectives of the SCALE initiative should be incorporated in REACH in order to emphasize the importance of early life exposure to VHC chemicals. This would also ensure that REACH's proposals reflect evolving information on early life toxic exposures, and identify critical research gaps.

It is clear that a wide range of considerations afford a more than adequate basis for strengthening REACH (Table 3).

THE GLOBAL IMPACT OF REACH

It must be stressed that despite major concessions, the fundamental principles of REACH remain intact and represent a unique and unprecedented complex of regulations for controlling the chemical industry, and reducing its major adverse public health and environmental impacts. This was emphasized by Environment Commissioner Margot Wallström in a November 15, 2003 letter to *The Financial Times*. "The chemicals reform is a test case for the principle of sustainable development. To be sustainable, any policy has to reconcile economic, social and environmental concerns. Achieving this balance is particularly important in the case of chemicals, where the stakes are so high on all three sides. It is high time that European citizens got the high level of protection for environment and health they have the right to expect. This is why we need a new strategy for chemicals management, and we should never forget this."

In fact, the changes needed to restore the integrity of REACH require relatively few modifications, just a few paragraphs or so, in the in 1,200-page 2003 legislative proposals. These changes could be readily made by Parliament in its second and third readings of the proposals.

Even more critically, Europe as the world's largest chemical market, has precedential ability to catalyze drastic reform of global legislative policies on the regulation of industrial chemicals. It should further be stressed that European regulations have far exceeded those of the U.S. since the 1990's (Table 11).

REACH has dramatically emphasized the inadequacies of the 1976 U.S. Toxic Substances Act, whose regulations still require testing of only about 5% of chemicals in commerce (21). Reflecting such concerns, exacerbated by the de-regulation policies of the Bush Administration, progressive Congressional Democrats are now drafting a proposal to overhaul U.S. regulations to conform with those of REACH. These initiatives are likely to extend to the State level, and have already been effected at the city level by San Francisco.

**TABLE 11: COMPARISON OF HEALTH AND ENVIRONMENTAL REGULATIONS
IN EUROPE AND THE U.S.⁽⁸⁶⁾**

UP TO 1970's

Regulation of risk was more vigorous in the U.S.

UP TO 1990's

The EC made great progress in regulation, and nearly closed the gap with the U.S.

FROM 1990's

Regulation of risk in the EC has far exceeded that in the U.S.

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ACRONYMS AND ABBREVIATIONS

ACC	American Chemistry Council
ARTAC	Association Française pour la Recherche Thérapeutique Anti-Cancéreuse
CDC	Centers for Disease Control and Prevention
CEFIC	European Chemical Industry Council
CMA	Chemical Manufacturers Association
CMR	Carcinogens, Mutagens, Reprotoxins
CPC	Cancer Prevention Coalition
CSR	Chemical Safety Report
EC	European Commission
ECB	European Chemicals Bureau
EDC	Endocrine Disruptive Chemicals
EEB	European Environmental Bureau
EPER	European Pollutant Emission Register
HPV	High Production Volume
IARC	International Agency for Research on Cancer
OCP	organochlorine pesticides
p.a.	per annum
PAN	Pesticide Action Network
PBT	Persistent, Bioaccumulative, Toxic
PIC	Prior Informed Consent
POP	Persistent Organic Pollutants
ppb	parts per billion
QSAR	Quantitative Structure Activity Relationships
REACH	Registration, Evaluation, and Authorization of Chemicals
SIDS	Screening Information Data-Sets
t.	ton
TUTB	Trade Union Technical Bureau
VHC	Very High Concern
vPvB	very Persistent very Bioaccumulative
WHO	World Health Organization
WTO	World Trade Organization
WWF-U.K.	World Wildlife Fund – U.K.