Deficits in US and European chemicals legislation – reform efforts and the transatlantic openness for dialogue

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1. Introduction

Modern chemistry has played an important role in the development of products that serve society's needs. However, there is increasing evidence that chemicals may also present risks to human and ecosystem health. Human exposure to potentially toxic chemicals can occur in several ways: directly from production and resulting emissions; when chemicals are sent to down-stream users for further processing (sometimes requiring several stages); in final production; and in product use and disposal. In some cases, depending on the properties of the chemicals, they reach the consumer directly. The direct processing and manufacturing of a product, or the chemical(s) contained within it specifically, creates a unique opportunity for a elevated exposure levels for workers.

Since it is well established that some chemicals can be acutely toxic (causing short-term injury) and can result in long-term harmful effects after longer periods of regular exposure, or exposures at particularly vulnerable times in development (in utero or childhood), protection measures must be implemented, particularly in the workplace. In Germany these provisions include:

- Substitution of hazardous chemicals with best available, less hazardous alternatives
- Minimizing human exposure to hazardous substances by choosing and designing suitable and safe work processes
- Minimizing the number of persons exposed to the substances
- Labelling the workplaces and risk areas with the corresponding warning signs and symbols
- Engineering and technical controls such as ventilation
- Personal protective equipment for members of staff
- As a last resort, prohibition of the manufacture and/or use of the substance.

These measures, however, can only be taken if the health (or ecosystem) hazards of the substances are known. Additionally, a clear assessment of risk is dependant on how long the body is exposed to a chemical (including those released from commercial items), as well as the type of this exposure (intensity, short, periodic, etc.). Thirdly, these measures are designed with the safety of workers involved with the production of products and their use in mind, but. do not generally address the problems of exposure throughout a chemical's lifecycle (for example to consumers or communities).

Chemicals policy and chemicals legislation takes an integrated approach to collecting and organizing available information to better understand chemical hazards, exposures, and risks, and

to ensure that necessary protection measures are implemented through personal protective measures, or bans and restrictions of hazardous chemicals.

For this to happen in industrialized nations, more than 30 years of comprehensive research must be reviewed. In this article, we will examine chemical assessment and chemicals management policies of Europe and the U.S, and discuss directions for the future of chemicals legislations.

2. Chemicals legislation in the U.S.

While the Toxic Substances Control Act is the standard for US national chemical regulation, regions and states rely on many different regulations to protect the public from hazardous substances, and therefore, there is no one US chemicals policy.

2.1 Overview

The lack of government oversight of chemicals in commerce changed with the passage of the Toxic Substances Control Act (TSCA) in 1976 (2). Earlier regulation on clean water and air had addressed primarily wastes coming from production processes. These acts generally placed the burden on the Environmental Protection Agency (EPA) to establish standards and demonstrate risks before acting. However, TSCA for the first time exerted government control over production and use decisions, affecting the types of chemicals that could be produced and limitations on their use.

It is important to note that TSCA's provisions apply differently to new and existing chemicals. A "new chemical substance" is defined as "any chemical substance which is **not** included in the chemical substance list compiled and published under [TSCA] section 8(b)." This list, called the "TSCA Inventory," is a list of all chemical substances in commerce prior to December, 1979. *All chemicals on the market prior to this date (about 60,000 substances, (3) more than 99% by volume of what is on the market today, are considered existing chemical substances. These chemicals are considered safe unless EPA can demonstrate that they present an unreasonable risk to human health or the environment.*

TSCA contains a number of additional key provisions which include the following:

- Section 4: Compels the EPA Administrator to require the testing of **new or existing** chemical substances or mixtures, , if 1) there are insufficient data to make an unreasonable risk determination; and 2) the chemical substance or mixture may present an unreasonable risk, or the chemical will be produced in substantial quantities and may either enter the environment in large quantities, or lead to significant human exposure.
- Section 5: Prohibits the manufacture, processing, or import of a "**new chemical substance**" or "significant new use" of an existing substance unless a premanufacture notification (**PMN**) is submitted to EPA no less than 90 days before the commencement of manufacture or processing. The PMN contains information on chemical identity, physical characteristics, processing and use, and available toxicity data. During this 90-day period, EPA reviews the chemical's human and environmental risks and exposures,

examining the data submitted in addition to other information. EPA can then request more data, prohibit or limit manufacture, or halt the review process.

- Section 6: Authorizes the EPA to issue regulations to address the risks of **existing substances** if "there is a reasonable basis to conclude that . . . a chemical substance or mixture . . . *presents or will present an unreasonable risk of injury to health or the environment* using the least burdensome requirements" that are necessary to address that risk. Such regulations can be issued immediately when a threat of harm is imminent.

- Section 8: Authorizes EPA to promulgate rules that require chemical manufacturers, processors, and distributors to maintain **records** and make **reports** on chemicals and mixtures. This includes requirements to submit health and safety studies, provide immediate notice of "*substantial risks,*" and maintain records of adverse health effects for 30 years.

What are the successes and failures seen after 30 years of TSCA (4)?

2.2 TSCA successes

Perhaps the greatest impact of TSCA has been its new chemicals review process. The TSCA provisions for new substances apply at the premanufacture stage (before any marketing has occurred) and place a medium initial threshold for agency action if substances "*may present an unreasonable risk to human health or the environment or substantial exposure throughout their production, use, and disposal.*" In conducting the premanufacture reviews, the EPA uses a multidisciplinary lifecycle review approach involving long-standing agency scientists to rapidly assess the risks associated with new chemicals. Through *deterrence* from potentially harmful chemicals and *guidance* toward safer chemicals and production methods, the EPA provides strong signals to manufacturers as to types of chemicals that might present an unreasonable risk and types of chemicals and synthesis pathways that will reduce risks. This provides an opportunity for the EPA to encourage development of safer chemicals and processes in the field of new substances (5).

Another information success has been the requirement under TSCA Section 8 that any chemical manufacturer, processor, or distributor who becomes aware of new information which indicates that their chemicals present a substantial risk of injury to human health or the environment must report the information to the EPA. The purpose of this requirement is to provide an early warning system. While early on there were few submissions of substantial risk under this provision, following a 1991-1994 "amnesty", more than 120 companies sent the EPA 11,000 studies or reports of adverse health effects from chemicals on the market that may have never been reported in the scientific literature. Since then, there has been a steady flow of studies into this "significant risk" database. This section also allows EPA to issue rules to collect production and use information as well as information on disposal and byproducts. This includes the Inventory Update Rule, which generates an inventory every four years of all of the non-polymer chemicals produced or imported into the United States (6).

2.3 Deficits

Despite the years of debate over TSCA and great hopes that it would help eliminate a substantial gap in regulation of toxic substances, its implementation has been less than successful, particularly in the field of existing substances. For restrictions on the manufacture or use of toxic chemicals the EPA has extremely high hurdles to take for existing substances before acting under TSCA. This has greatly limited the numbers of chemical restrictions to date (though reductions in use of some chemicals such as chlorinated solvents have been achieved through various voluntary programs) (7). To restrict such chemicals EPA must prove that the chemical "will present an unreasonable risk", that it is choosing the least burdensome regulation to reduce risks to a reasonable level, and that the benefits of regulation outweigh the costs to industry. EPA must do this on a chemical-by-chemical basis.

Studies in the 1980s and 1990s by the National Academy of Sciences, the Environmental Defence Fund and the Environmental Protection Agency demonstrated that most industrial chemicals had not undergone even basic toxicological testing. The EPA used these reports to reach a voluntary agreement with the American Chemistry Council which stated that industry would provide basic screening level data on the high production volume (HPV) chemicals - the 2,800 chemicals manufactured or imported in quantities over 1 million American pounds per year (about 500 metric tonnes). The programme to date has been moderately successful, with industry consortia having completed their work on about 65 percent of the chemicals and producing comprehensive lists of toxicity data. Although the EPA has made the data available on the Internet (8),the agency has yet to determine how to use incoming data for risk management decisions. While the HPV agreement has certainly generated a large quantity of important hazard information in a short period of time, the programme, however, does not cover the more than 6,000 middle range existing production chemicals currently used annually in quantities between 5 and 500 tonnes.

Further, EPA's ability to provide public information on chemical production and risk has also been hindered by strict confidential business information provisions of TSCA. During the early history of TSCA, industry had to substantiate confidentiality claims. Confidentiality claims now, however, require little more than a routine check-off procedure. A 1998 EPA analysis found that 65 percent of the information in industry filings to the agency under TSCA was claimed as confidential. In about 40 percent of substantial risk notification cases, chemical identity was claimed as confidential (9). Table 1 shows what has been achieved in the TSCA framework.

Several government reviews have demonstrated the failure of TSCA to manage existing chemicals. A 1994 report by the U.S. Government Accounting Office (GAO) found that throughout its existence EPA has restricted only **five chemicals** (PCBs, chlorofluorocarbons, dioxin in production waste, asbestos, and hexavalent chromium) (10). Congressional hearings in 1983, 1988, and 1994 highlighted the limitations of the EPA's existing chemicals programme. In 1988, Charles Elkins, then head of the EPA's Office of Toxic Substances, noted: "In my opinion, that which has been achieved under the existing chemicals programme is clearly inadequate." (11)

Table 1: EPA Chemicals Program Activities (12)

Existing Chemicals (1977-1994)	
	Number Issued/Completed
Section 6B Restrictions	5 (through 2003)
Section 4 Test rules	30 (121 chemicals)
Testing consent agreements	59
Chemical risk assessments	1200 (30-40/year)

Regulatory Action	**Number Issued**
Section 5(e) test/restriction orders	743
Significant New Use Rules	937
Section 5(f) restriction actions	4
PMNs withdrawn in face of action	1,552
Voluntary testing actions	300
Total cases regulated	**3,532**

Example: Asbestos and the limits of TSCA.

The EPA's experience in attempting to regulate asbestos in 1990, demonstrates the near impossibility for EPA to restrict **chemicals in commerce** through regulatory means. Following ten years of research, public meetings, and regulatory impact analyses in 1989 the EPA issued a final rule under Section 6 of TSCA to prohibit the future manufacture, importation, and distribution of asbestos in almost all products. The asbestos industry challenged the EPA's ban and took its appeal to the Fifth Circuit Court of Appeals. In a landmark case (*Corrosion Proof Fittings v. EPA)*, the court all but eliminated the EPA's ability to use TSCA Section 6 to restrict problem chemicals (13). Overall, the court held that the EPA had presented insufficient evidence (including risk information) to justify its asbestos ban. The court found that: (a) the agency had not used the least burdensome regulation to achieve its goal of minimising risk, (b) had not demonstrated a reasonable basis for the regulatory action, and (c) had not adequately balanced the benefits of the restriction against the costs to industry. In its conclusions the court held that *"the EPA's regulation cannot stand if there is any other regulation that would achieve an acceptable level of risk as mandated by* TSCA" and that *"EPA, in its zeal to ban any and all asbestos products, basically ignored the cost side of the TSCA equation."* Such a sharp reprimand from the court has reduced any further efforts by the EPA to use its Section 6 authority to restrict chemical production or use, to almost zero.

2.4 States act to reverse the trend

In light of the failure at the federal level to establish relevant regulations on chemicals management for existing substances, a number of states have seen a need to take action on their own. Massachusetts and New Jersey have successfully implemented mandatory pollution prevention planning regulations state-wide (14).

For example, the Massachusetts Toxics Use Reduction Act, passed in 1989, requires that manufacturing firms processing more than 4.5 t (10,000 lbs.) per year of regulated substances annually calculate their toxic materials use and waste generation (15). They must then develop plans and thoroughly examine options to reduce their waste and used quantity of these substances and measure progress. Summaries of these plans and materials accounting data are publicly available. Fees on the chemicals used provide funds for the regulatory programme, as well as voluntary technical assistance to industry, and a research and training programme to assist firms and communities in seeking safer chemicals, processes, and products.

Over a ten-year period, toxic chemical emissions in Massachusetts have been reduced more than 80 percent; toxic waste, almost 60 percent; and toxics use, almost 40 percent, indexed for changes in manufacturing activity. Massachusetts firms have saved more than $15 million in the process, excluding the unquantifiable benefits to health and the environment (16). The toxics use reduction programme, however, only applies to manufacturing firms in Massachusetts and therefore does not include chemicals in products made outside of the state. New legislation, called the Act for a Healthy Massachusetts, being discussed to extend the toxics use reduction model to products produced and imported into the state. The law would initially require the development of substitution action plans (identifying major uses of the chemical and safer subtitutes for those uses) for ten priority chemicals and establish a process for adding additional chemicals to the substitution planning process.

Since the late 1990s, several states and localities have initiated both voluntary and mandatory programmes to reduce the use of persistent, bioaccumulative and toxic substances (PBTs). In 1998 Washington State approved a state-wide policy for eliminating pollution caused by PBTs (17), designating nine PBTs for reduction, and including 13 more in the "PBT Working List" of chemicals on which to focus in future action plans. The state Department of Ecology is implementing the programme through monitoring, public education and outreach, research, and procurement. Several states, including New Hampshire, Vermont, Maine, Rhode Island, Oregon and Connecticut, have passed legislation to phase-out the use of mercury in various consumer products. Other states such as California have enacted, or are considering legislation, to phase out polybrominated diphenyl ethers commonly used as flame retardants (18), while the San Francisco bay area has established procurement policies which prohibit the use of certain chemicals and encourage the purchasing of others in government contracts (19).

These examples show how change and incentives for improving chemicals policy in the US in the past few years has essentially been initiated by individual states. This trend will most likely continue, but does not come without risks to a uniform US chemicals policy.

2.5 Conclusion of USA

Although the EPA has successfully reviewed new chemicals that have come on the market since 1980, there is a stark discrepancy between new chemicals and existing chemicals regulations in the United States. The TSCA programme has been considered by many analysts and EPA officials to be a failure in regulating existing chemicals. The entire burden of prove that an existing chemical substance will present an unreasonable risk, and that the benefits of regulation outweigh the costs, rests on the EPA. Data uncertainty thus favours keeping existing chemicals on the market. Indeed, the EPA's lack of power to regulate existing chemicals could actually provide a disincentive to developing and bringing safer new substances to market. Dr. Lynn Goldman, former EPA Deputy Administrator for the Office of Prevention, Pesticides and Toxic Substances, has effectively summarised the failures of TSCA (20):
"It is fair to state that the results [of TSCA] have come nowhere close to…the original Congressional intent… Although Congress has shown little interest in doing so, there are many examples of sections that need to be reformed and strengthened. Probably the weakest area concerns the management of risks from chemicals. Because of the Act's inadequate coverage, when EPA is confronted with new risks…it is unable or unwilling to take action to reduce risks, unless industry is willing to step forward voluntarily on its own. TSCA currently places too high of a bar for the EPA to jump to assure the health of the public and protection of the environment. Under TSCA, existing chemicals are assumed safe until proven guilty, even when found in breast milk and even as toxicology evidence accumulates."

While the EPA has argued that TSCA requires the agency to engage in voluntary initiatives, the rationale for such initiatives is one less of mandate than of necessity and design of TSCA. It is impossible for the EPA to regulate chemicals in commerce, so the agency is forced to rely on voluntary initiatives such as the HPV challenge programme and others to gather necessary data and encourage industry to undertake risk management measures. While the EPA has successfully promoted important and highly appreciated voluntary efforts such as Design for Environment (21), Green Chemistry (22), and sector based pollution prevention programmes such as the Cleaner Technologies Substitutes Assessment (23), or the Persistent Bioaccumulative and Toxic Substances programme (24), they are insufficient to ensure that basic data are available on chemicals in use, or that EPA has an ability to act to restrict problem or broad classes of chemicals. The existing provisions of TSCA could be used more effectively by the EPA by applying stronger political determination, but the agency will be unable to substantially address chemical risks to public health or the environment without major revisions to this central chemicals management policy statute.

As has traditionally been the case in the United States, state and regional authorities will continue to be the innovators of chemicals management policy in the coming years. This will, however, jeopardize the development of a uniform US market.

3. Chemicals legislation in the EU

Europe, in the following text, shall mean the European Union (EU) which grew originally from six Member States, to 25 to date (25). Over the past few years chemicals legislation in Europe has been widely harmonized between nations while being centrally controlled. The Member States

fully participate in the legislation process and have the duty to implement and enforce EU legislation. In EU legislation, a distinction is made between directives (which are to be transposed into Member States' own national laws) and regulations which apply directly (26).

3.1 Overview

In the 1960s, regulations on **classification, labelling and packaging** of hazardous substances were harmonized, throughout Europe, by the Chemicals Directive, 67/548/EEC (27). Later, with the Chemical Directive 92/32/EWG ,the basic definitions used in European chemicals law were added; specific hazardous characteristics such as carcinogenity, mutagenity, and toxicity for reproduction; in its technical annexes, lists the substances that are classified as dangerous, throughout Europe (Annex I); lists the European symbols and indications of danger for dangerous substances and preparations (Annex II) and the labelling with prescribed risk and safety phrases (R and S phrases, Annexes III and IV); and lists the methods used for detection of physico-chemical properties, toxicity and ecotoxicity (Annex V).

In 1988, the general directive on preparations 88/379/EEC was adopted (28), which introduced classification criteria for all hazardous **preparations** (mixtures of two or more substances). Pursuant to this directive, hazardousness of preparations is normally determined on the basis of the preparations' concentrations of already classified individual substances.

A directive for new substances was adopted as early as in 1967 (67/548/EEC) which required the registration of new substances with the competent authority of the Member State before they were placed on the market. Pursuant to Art. 16 (1) of this directive, the relevant Member State registration agency carries out risk assessment, a process that includes making recommendations for measures to reduce the risks for man and the environment, arising in connection with the substance in question. To prevent differences in assessments made by different Member States, the Commission additionally adopted "Directive 93/67/EEC of 20 July 1993 laying down the principles for assessment of risks to man and the environment" (29).

In 1976, Directive 76/769/EEC laid the foundation for organizing consistent **prohibitions and restrictions** on the marketing of certain dangerous substances throughout Europe (30). The directive sets the framework in which prohibitions and restrictions can be issued. These measures are to be legally implemented and enforced in the Member States. Polychlorinated biphenyls (PCB) and terphenyls (PCT) were the first substances to be restricted. There were a series of subsequent cases in which the opportunities offered by the directive were made use of. Politicians and administrators mainly used the directive to reduce or eliminate identified risks of great relevance.

Table 3 provides an overview of provisions to date under this directive, as well as an overview of the topics currently under discussion.

In 1993, the Existing Substances Regulation was adopted, which is designed to regulate the assessment of existing chemicals (31).The regulation provides for systematic collection of available data and for risk assessment with the help of priority lists. In a first stage, certain minimum data, along with available chemical-physical, and existing human-toxicity and eco-

toxicity data, had to be supplied by 5 June 1994 for substances listed in Annex I of the Regulation that are sold in volumes of at least 1,000 tonnes annually. In a second stage, beginning on 5 June 1996 and lasting until no later than 5 June 1998, such data also had to be submitted to the EU Commission for substances sold in amounts of 10 to 1,000 tonnes annually.

The list compiled in the context of Councel Regulation 793/93 (32) of the substances existing in Europe covers 100,000 entries (European Inventory of Existing Chemical Substances = EINECS (33)) and includes about 40,000 substances more than the corresponding U.S. list. The reservoir, EU companies can draw from for developing new applications of already **existing substances** is thus significantly larger. This economic advantage is part of the current transatlantic discussions on chemicals policy (see below).

3.2 Successes

Overall, Europe's standardized substances laws – laws developed during the 1970s and 1980s- must be considered a success. The discrepancies resulting from differences in special national regulations have been gradually overcome. Another major success is that a standardized regime for registering new substances has been established and implemented.

In Europe, a binding registration procedure exists only for new substances at present. The manufacturer or importer wanting to market more than 10 kg per year of a substance that was not manufactured in the past must register the substance with the competent authority. A basic data set needs to be transmitted for volumes of more than 1 t per year, to enable a first assessment of hazards to the environment and health. This is primarily aimed at identifying acute effects such as toxicity for both human health and the environment. In case of a volume of more than 100 t/a, studies must be undertaken for an evaluation of long-term harmful effects to determine if a substance is carcinogenic or mutagenic in long-term exposure. Since 1981, more than 3,700 new substances have been registered in the European Union.

Numerous successes have also been achieved with regard to existing substances. For example, in the past 20 years, prohibitions and restrictions have been implemented for various risky chemical applications (Tab. 3). On the other hand, although the list in Table 3 might appear to be long, such measures have not been numerous compared to the heap of problems in connection with about 100,000 existing substances. Furthermore, these individual decisions (prohibitions and restrictions) have not been taken on the basis of a scientific process of establishing priorities among all the existing substances but of accidental scientific findings and included medial components in the political decision making process.

Another positive result is that it has been possible to gather information about existing substances' effects. At the same time, this success has been rather modest, since the relevant effort has had to rely on voluntary data provision, and only limited data has been provided.

Table 3: Restrictions on the placing on the market and use of certain hazardous substances and preparations in the EU, as of 2004 (CMR= carcinogenic, mutagenic, reproduction toxic)

Directives for amendment and adaptation	**Date**	**Substance**	**Restriction on placing on the market and use**	**Entry into force**
Basic directive	27.07.1976	Polychlorinated biphenyls (PCB) and terphenyls (PCT) Vinyl chloride (VC)	Partial restriction on open use of PCB and PCT; Prohibition on use of VC as an aerosol propellant	Jan. 1978
1st Amendment	24.07.1979	Hazardous liquids	Hazardous liquids in ornamental objects / toys	July 1980
2nd Amendment	22.11.1982	Benzene	Benzene in substances, preparations and toys	Nov. 1983
3rd Amendment	03.12.1982	PCT	PCT-containing material for structural components	Dec. 1982
4th Amendment	16.05.1983	Polybrominated Biphenyl (PBB)	PBB in textiles	Nov. 1985
5th Amendment	19.09.1983	Blue asbestos	Blue asbestos in products	March 1986
6th Amendment	01.10.1985	PCB, PCT,	Special provisions regarding labelling of products containing PCB and PCT	June 1986
7th Amendment	20.12.1985	Crysotile asbestos	Prohibitions applying to a range of articles, including toys, smokers' products, catalytic sieves	Dec. 1987
1st Adaptation	03.12.1991	Asbestos (blue asbestos), crysotile asbestos	Other prohibitions, including prohibitions on use in mortar, coatings and paints, roof tarpaper	July 1993
6th Adaptation	26.07.1999	Asbestos	Nearly complete prohibition (with an exception for diaphragms)	Aug. 1999
8th Amendment	21.12.1989	Hazardous liquid substances; Lead, arsenic, mercury, organotin compounds	Prohibition on use of such liquids in ornamental objects (including lamps); Restriction on use as biocidal agent	June 1991
4th Adaptation	10.09.1997	Hazardous liquid substances	Tightening of regulations for lamp oils, from the 8th directive for amendment	Dec. 1998
10th Adaptation	06.01.2003	Arsenic compounds	As biocidal agent; treated wood	Jan. 2003

Directives for amendment and adaptation	Date	Substance	Restriction on placing on the market and use	Entry into force
9th Amendment	21.03.1991	Pentachlorophenol (PCP)	Prohibition on use for wood treatment	June 1992
10th Amendment	18.06.1991	Cadmium and cadmium compounds	Restriction on use of Cd as stabiliser and colouring agent in PVC	Dec. 1992
5th Adaptation	26.05.1999	Tin, PCP, cadmium	Tightening of provisions on tin, PCP and Cd set forth by the 9th and 10th directives for amendment	June 1999
11th Amendment	18.06.1991	Ugilec, DBBT	Complete prohibition on use	June 1992
12th Amendment	30.06.1994	Nickel and nickel compounds	Prohibition on use in commodities (rings, buttons, etc.)	Jan. 2000
13th Amendment	07.12.1994	Flammable substances	Prohibition on use of flammable substances in aerosol packages intended for ornamental purposes	Dec. 1995
14th Amendment	20.12.1994	CMR substances, CHCs Creosote	Prohibition on sale of CMR substances and CHC substances to private end consumers; Restrictions on use of creosote for wood treatment	June 1996
2nd Adaptation	04.09.1996	Chlorinated Solvents	Tightening of regulations for CHCs, from the 14h directive for amendment	June 1998
3rd Adaptation	26.02.1997	CMR substances	Prohibition on sale of other CMR substances to private end consumers	June 1998
7th Adaptation	26.10.2001	Creosote	Tightening of regulations for tar oils, from the 14h directive for amendment	June 2003
15th Amendment	10.04.1997	Hexachloroethane	Prohibition on use of hexachloroethane in production or processing of nonmetals	May 1997
8th Adaptation	29.10.2001	Hexachloroethane	Elimination of the exceptions permitted under the 15th directive for amendment	Nov. 2001

Directives for amendment and adaptation	Date	Substance	Restriction on placing on the market and use	Entry into force
16th Amendment	20.10.1997	CMR substances	Prohibition of substances classified as carcinogenic, mutagenic or harmful to reproduction (CMR substances)	March 1999
17th Amendment	25.05.1999	CMR substances	Expansion of the Annex to 16th directive for amendment, to include additional substances	July 1999
19th Amendment	19.07.2002	Azo dyestuffs	Prohibition on use of azo dyestuffs in textiles, leather and toys	Sept. 2002
12th Adaptation	06.01.2003	Azo dyestuffs	Announcement of test procedures for proving the presence of amines in leather and textiles	June 2004
13th Adaptation	24.02.2004	Azo dyestuffs	Announcement of test procedures for azo dyestuffs	March 2004
20th Amendment	25.06.2002	Short-chain chloroparaffins	Prohibition on use of short-chain chloroparaffins in metal processing and in oiling of leather	Jan. 2004
21st Amendment	19.06.2001	CMR substances	Expansion of the Annex to the 14th directive for amendment, to include additional CMR substances	Jan. 2003
23rd Amendment	26.05.2003	CMR substances	Expansion of the Annex to 14th directive for amendment, to include additional CMR substances	July 2003
24th Amendment	06.02.2003	Penta-, octa-bromodiphenylether	Prohibition on use as flame retardants	Aug. 2004
25th Amendment	26.05.2003	CMR substances	Expansion of the Annex to 14th directive for amendment, to include additional CMR substances	June 2003
26th Amendment	18.06.2003	Nonylphenol (NP), nonyl-phenolethoxylates (NPE), chromate-containing cement	Prohibition on use of NP and NPE in cleansers; Restriction of the Cr(VI) content of cement	Jan. 2005
Restriction measures for which consultations are pending				

Directives for amendment and adaptation	Date	Substance	Restriction on placing on the market and use	Entry into force
		Dichloromethane	Prohibition of sale to private end consumers; restrictions on professional use	
		Organotin compounds	Prohibition on use of organotin compounds in wood treatments and commodities	
		Acrylamide	Prohibition on use of acrylamide in sealing mortars	
		Cadmium	Restriction of recycling of cadmium-containing PVC to a small number of products for construction	
		Toluene	Limits on toluene concentrations in spray paints (0.1%)	
		PAH	Limits on PAH concentrations in tyre oils (< 1 mg BaP / kg) and tyres	
		PFOS/PFOA	Restriction	

3.3 Deficits

Only when substances are tested do their harmful properties become apparent, and only then are substances classified according to these properties and warnings issued (safety notices) for their use. More than 100,000 existing substances are registered in the European Inventory of Existing Chemical Substances that have been only minimally tested for toxicity. About 30,000 of these are produced or imported in volumes over 1 t/a. The EU lists of substances officially classified as hazardous substances cover only about 3,000 substances.

Roughly half of new chemicals, which receive systematic testing are classified as hazardous. Since there is no particular scientific reason why new substances should be more dangerous than existing ones, one could estimate that the percentage of substances classified as dangerous will be similarly high for existing chemicals once tested. As such, because they are not labelled or subject to risk management measures, they can pose elevated human health risks

The main problem of the current provisions of European chemicals legislation lies in the lack of sufficient information on about 100,000 substances (or 30,000 substance > 1 t/a) which have been used for more than 20 years, (about 97 % by volume of all substances marketed). These substances did not need to be tested nor evaluated before 1993 and could be marketed without any conditions. The EC Regulation on existing substances entered into force in 1993 and

stipulated that available data must be provided for marketing volumes of more than 10 t/a. This data, however, has largely not been detailed enough for sufficient evaluation, and in many cases the effects that production and use of the material may have on the environment or on human health are hardly known.

Identifying priority substances within the mountain of existing substances by establishing risk categories and implementing them was not successful either. Basic data sets needed to be presented for 140 substances included in the EU priority lists; but the evaluation was completed in only 30 cases (cf. Tab. 4). This inevitably led to risk management strategies for substances which are a hazard to human health and the environment that were incomplete and unsystematic . Matters are further complicated because the state must prove that a substance poses a risk and needs to be regulated, but is dependent on manufacturers for providing the necessary data.

Things look even worse for the second half of risk assessment: risk management. In Europe, risk reduction measures have been carried out in only **six** cases since 1993. Moreover, in practice, decisions on restrictions have often not been made until very concrete hazards have become apparent or high risks have emerged (34, 35). Existing European chemicals laws incidentally do not provide possibilities for **precautionary** risk minimisation.

Table 4: Status of assessment of existing substances in the EU

Total number of existing substances	100,000 (or 30,000)
Number of prioritary substances to be included	**2,700**
Priority substances (4 lists)	**141**
substances assessed to date	**80** - comprehensive risk assessment: 66 - only environmental assessment: 7 - only employees/consumers: 7
Risk declaration on the basis of risk assessment	**53** (at least one of the protection areas – environment, employees, consumers – is affected)
Substances for which risk-minimisation measures have been proposed	**32** - measures pertaining to employees: 26 - Measures pertaining to consumers: 17 - Measures pertaining to the environment: 22
Substances for which risk-minimisation measures have been accepted	17; with recommendations being issued for additional measures for 12 substances in this group
Substances for which risk-minimisation measures have been implemented	**6**

3.4 REACH, the answer

The discussions on chemicals policy reform over the past several years in Europe have led to an increased public understanding of the deficits of current chemicals policy and the need for a new approach to achieve more sustainable chemicals management. The European REACH proposal (36) responds to growing concerns about the impacts of toxic substances on health and the environment, and about the deficits of the existing chemicals regulatory framework that permits chemicals to be considered safe until proven harmful, even when little information about their health impacts is available.

Pursuant to the planned REACH Regulation (Registration, Evaluation and Authorisation of Chemicals), a company that produces or imports a chemical substance in amounts of more than 1 t/a must test the substance for impacts on human health and the environment, and must register it in a central database. The testing requirements are outlined in Table 5. In each case, such basic information is forwarded through the supply chain, so that users of chemicals will also be able to use chemicals safely, in keeping with the latest relevant findings. In cases involving substances that are produced in especially large amounts or that create cause for concern, the data will be checked by authorities, and additional data requirements will be imposed as necessary. In addition, a simplified procedure, in comparison to that under existing law, will be introduced for issuing prohibitions and restrictions (see above) with regard to hazardous substances so that the decision making process is significantly shortened through a leaner process. All in all, the new system is aimed primarily at making industry largely responsible for managing risks presented by chemicals and for providing information on safe use of chemicals.

Table 5: Future requirements for testing of existing chemicals (existing substances)

> 1 t/a	> 10 t/a	> 100 t/a	> 1,000 t/a
Skin irritation	In vivo skin-irritation test		
Eye irritation	In vivo eye-irritation test		
Skin sensitivity			
Mutagenicity in vitro, Ames test	In vitro gene-mutation test with mammalian cells		
	In vitro cytogenetic test		
	Acute tox.		
	28-day test		If necessary, long-term tox. > 12 months
	Screening, Reproduction test	Reproduction toxicity for an animal species	
			Two-generation reprotox.
Short-term tox. Daphnia		Long-term test with daphnia	

> 1 t/a	> 10 t/a	> 100 t/a	> 1,000 t/a
	Inhibition of algae growth		
	Short-term tox. Fish	Long-term tox., fish	
	Adsorption-desorption screening test	Additional testing, adsorption-desorption	
		Accumulation in fish	
		Short-term test, earthworms	Long-term test, earthworms
			Long-term tox., invertebrates
			Long-term tox., birds
		Short-term tox., plants	Long-term tox., plants

All relevant data for toxicological and ecotoxicological evaluation will be made available to the public (right to know). A new European central authority for chemical substances is to be established to administrate the database, accept registration dossiers, and make non-confidential information available to the public. It is expected that 80 % of all registration dossiers will not require any further processing. This figure gives an indication of the extent to which the new system transfers the burden of proving chemical safety to industry.

Authorities will prioritize substances that are produced in large amounts or that indicate they may be of concern. Both dossiers and substances will be assessed.

Dossier assessment will be required in cases in which proposals for further animal testing are made in the framework of assessment; such proposals are made, for example, for substances produced in amounts of over 100 t/a. The testing regulations have been framed with a view to avoiding animal testing wherever possible; for this reason, in each case the competent authority is to become involved before more extensive testing is carried out. Dossier assessment is also intended as a vehicle for general review of the extent to which registrations conform to regulations.

Furthermore, the competent authorities should be able to assess any substance about which they have a reasoned suspicion that the substance could pose a hazard to human health or to the environment. The main thrust of this form of assessment is to obtain a better understanding of a substance's characteristics and to gain a better position for determining whether further risk-management steps are required.

The REACH system is based on the assumption that industry would normally act under its own responsibility to control risks as necessary in light of findings gained about substances and provided through the supply chain. The regulation is also designed to improve the possibilities for state action in risk management, however. To this end, procedures for issuing prohibition and restriction regulations (see above) are to be significantly simplified; in future, the EU Commission will issue such regulations via a committee procedure.

Furthermore, under the REACH system, use of substances that give particular cause for concern can be made subject to EU Commission-issued certification known as "authorization". The "substances that give particular cause for concern" and that are to be made subject to this procedure include carcinogenic and mutagenic substances and substances harmful to reproduction (CMR), persistent, bioaccumulative and toxic substances (PBT), very persistent, very bioaccumulative substances (vPvB) and other substances with similar harmful effects on human health and the environment. Where the risks inherent in use of such substances are sufficiently controlled, authorization can be provided. Where the risks are not as well controlled, the EU Commission will review the extent of the risk, the substance's social and economic benefits and the availability of substitutes. Then it will decide on whether the substance can be authorised. Overall, the certification/authorisation regulations are expected to provide significant incentives for substitution of relevant substances with less hazardous substances or technologies.

3.5 Conclusion, Europe EU

For Europe, REACH is the answer to the above-described successes and deficits of existing chemicals law.

Currently, REACH is being debated very controversially in the EU. The legislative procedure, involving the two European legislative bodies (Council and Parliament), is in full swing. In light of the complexity of this subject, the legislative procedure is expected to take two years. In this period, corrections can be expected in some areas of regulation.

In parallel with the legislative procedure, administrative regulations are now being developed to make enforcement of the regulation easier and more specific (RIPS process (37)). This is in the interest of the affected players, because it will involve clearer stating of requirements.

There is no doubt that REACH will be introduced in Europe. It is clear that players in the U.S. and Asia remain in an observation role, though the U.S. government has so far taken a very negative stand on REACH (38). The coming two years will offer an opportunity to move ahead with reforms, aimed at solving the existing substances problem, in other economic areas with relevance for chemicals policy. It would make sense to strengthen the transatlantic constructive dialogue to facilitate a greater coordination of the regulations (see below).

Europe is currently preparing its domestic economy for the REACH process. Implementation is studied for medium-sized companies in particular (39), as is the RIPS process mentioned above works. The EU Commission has commissioned a thorough impact assessment of the effects of inter alia on medium-sized enterprises, trade, and industry in the 10 Member States which acceded on 1 May 2004. However, this process will need to be intensified. The EU Commission and the Member States will use the coming two years for this exercise.

4. Towards a transatlantic win-win situation

It is interesting to note that the problems of industrial-chemical risk assessment and the limitations in current regulatory approaches for addressing chemical risks are strikingly similar on both sides of the Atlantic. These include:

- A lack of information on most chemicals in commerce (existing substances and chemicals);
- a disconnect between regulatory concepts for new and existing chemicals;
- a slow and resource intensive risk assessment process for suspected health/environmentally harmful substances that places the regulatory burden on authorities;
- a lack of incentives for the substitution and innovation from problem chemicals to safer alternatives; and last, but not least,
- increasing evidence of the health effects associated with toxic substance exposure.

The difference in the political attitude in the European Union and the United States towards these problems is obvious. Where in Europe, efforts towards chemicals policy reform have been moving forward for more than five years and have led to the European Commission's publication of the Registration, Evaluation, and Authorization of Chemicals (REACH) proposal in October 2003 (36), there is no similar effort at the federal level in the United States.

The starting point and core concern to implement reforms in the chemicals legislation in the EU and the US should be the wish to eliminate the deficits described above. But this elimination of deficits is not an aim in itself, but rather a means to improve health protection at the workplace and for the consumers and to guarantee sufficient protection for the environment. The regulator would not take action primarily for reasons of precaution but for reducing the deficits in the field of hazard control.

A lot of reasons can be given why this aim should be reached in a joint transatlantic effort. Perhaps the core argument for outlining the rewards a continued dialogue would have, is to be found in the expectations of the people in Europe and the U.S. They would surely not understand and not accept it, if there were a substantial difference in the level of protection in these two world markets.

But besides health and environmental protection issues, there are also economic aspects to be taken into account. In Europe, industry has been tending to argue that the planned REACH system will put European companies at a competitive disadvantage in comparison to foreign companies, especially companies in the U.S. and Asia. For this reason, leading chemical industry associations have been speaking out against REACH.

If one accepts this argument, one must assume that U.S. companies have nothing to fear in REACH and would even welcome it. One would have to assume that REACH would give U.S. companies competitive advantages. **Nonetheless, the U.S. government, U.S. industry, including its chemical industry associations, has also been opposed to REACH.** For this reason, it is useful to take a closer look at the transatlantic situation.

In the medium term, REACH may actually give the European chemical industry a competitive advantage. The required tests and data documentation will make it easier to understand and more

effectively recognize the intrinsic effects of substances. Industry will be able to use the data pool that will become available in order to develop and obtain further findings.

A closer look shows that such new data cannot simply be seen as the fulfilment of burdensome state requirements. One of REACH's most important by-products in terms of economic policy will consist of new information and understanding of chemical structures and effects that will provide the basis for innovation within the European chemical industry. Companies that are able to derive substances' effects from chemical structures will have competitive advantages in competition for the development of safer substances or applications or for the selection of suitable substances from the pool of existing substances. In essence a greater awareness of chemical structures and effects will help enhance design of newer, safer chemicals as well as reduce liability for the effects caused by existing problematic ones.

A substance's effects are also tied to the way the substance is used, or to the "service" that is to be provided with the substance. For this reason, new findings in the areas of structures and effects can also lead to new developments in chemical production and processing and manufacturing of final products. There is a substantial literature about the innovation benefits of environmental regulations, such as REACH. Such regulations often produce side-benefits in innovation and development that were unexpected. For example, developing useful consumer products was not the primary purpose of the space programme. And yet technological progress via the space programme has produced innovations, as by-products, and has enabled the development of many new industrial fields.

REACH will enhance understanding of chemical "language" (structure – effect connection); in some areas, it may make it possible to decipher this language completely. Such knowledge can lead to many useful results and to the establishment of many new industrial areas and products.

There are many reasons why this development should be organised transatlantically, via international cooperation. Most importantly, chemicals trade is global in nature. According to the estimates of the European chemical industry, REACH will produce a data pool worth some € 10 billion. According to the EU Commission, however, this data pool is “only” worth € 2.3 billion. What ever its true value, key questions will include: who is to receive access to this data pool, and how should use of the pool data be organised? A scenario in which the U.S. reform their own chemicals laws would include making decisions on burden-sharing. To keep Europe from having to bear the entire burden of existing-substances assessment, U.S. industry should make a contribution approximately similar to that of European industry. This would halve the financial burden for European industry and would open the way to transatlantic use of the data pool. Benefits of REACH type policies should be globally distributed as well as the costs.

There is a new and important opportunity for transatlantic cooperation around data sharing for the development of safer substances. The U.S. House of Representatives recently unanimously passed the Green Chemistry Research and Development Act of 2004. This bill greatly expands federal funding for the development of safer chemicals and chemical processes (the current federal budget for safer chemistry amounts to about the cost of a single two year cancer study in rodents for a single chemical). This bill, which has received bipartisan support, will provide an important incentive for using new data on chemical structures in the development of safer chemistry.

It must also be assumed that REACH would expose considerable numbers of individual substances or applications to regulatory and market scrutiny, but would also show European and international industries and authorities where substitute substances are needed for health and safety reasons. A continuous, orderly reshaping process is expected, over the next 15 years, in which various existing substances, and special applications of such substances, will be changed in response to new findings. This process cannot be expected to remain confined to Europe as increasingly improving safety levels will have an impact on the U.S. market. In fact, existing European restrictions on chemicals are already forcing some U.S. companies to change production of products such as electronics to continue being able to sell products in the European Union. It will not be in U.S. industry's interests to have to play catch-up to these developments and information resources. In a "catch-up scenario", the U.S. would find itself on the defensive in the world market and would be confronted with requirements and information demands that it could not meet. For these reasons, in a desirable scenario, the U.S. would participate in the collection and assessment of safety information. This would take place automatically under a transatlantic consensus on joint existing-substances assessment. Current relevant work at the OECD (40) level provides a good illustration of how such consensus can be achieved (41, cf. Tab.6). It is certainly a modest example, but it shows clearly that burden sharing can work.

While the European Union efforts will have an effect on U.S. chemical production and regulation, in the spirit of transatlantic cooperation it is important that the European Union learn from the extensive lessons of US regulators on issues such as toxics use reduction, rapid screening of chemicals, and right to know.

Table 6: Status of international chemicals assessment at the OECD level (42)

1. Aim of the ICCA (43) voluntary commitment and of the OECD programme: provide data for 1,000 substances by the end of 2004 and obtain an internationally coordinated data set.
2. Current status of ICCA substances approval (including SIAM, 18): 219 substances
   of these, Europe: 122
   of these, U.S.: 48
   of these, Japan: 33
3. Aim: 1000 ICCA substances OECD-approved by the end of 2005
   Outlook: currently, about 100-120 substances are being processed per year; an additional 1000 substances will have to be processed in a later phase (under discussion)
4. Required OECD test data:
   Human toxicity:
   - acute toxicity
   - subacute toxicity
   - gene toxicity
   - reproduction toxicity: a) fertility, b) developmental toxicity

   Eco-toxicological test data:
   - Acute fish, daphnia and algae

   Exposure situations (this is required only in sponsor countries)

Finally, it must be noted that REACH has become a political issue. In the U.S. controversial discussion about protecting human health, consumers and the environment against hazardous

substances is taking place at the federal level (in the form of bipartisan debate) and at state level. As the above remarks indicate, the U.S. can expect to incur disparities in its own requirements for the chemical industry, with regard to production and products (such disparities have already appeared, in light of the initiatives in some states). This process will intensify in a scenario in which REACH is in operation in Europe and no relevant changes occur in the U.S. Such a development would not be in the interest of American industry.

A win-win situation is brought about when the collection of data for reasons of environmental protection and health protection enables the industry to generate new awareness and develop new markets. A win-win situation also exists if Europe opens up further to U.S. knowledge in substance assessment (see above) and if the U.S. government goes ahead with regulatory efforts to eliminate the deficits in U.S. legislation on chemical substances. This would be the scenario in which to negotiate about burden sharing between the industries in the U.S. and Europe. Sharing the burden also entails sharing the benefit. Such a process can be organized within the next two years (prior to the adoption of REACH)!

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