

Economic Effects of the EU Substances Policy

**Supplement to the
Report on the BDI* Research Project
18th December 2002**

"Analysis of the Effects of the Legislation Proposal October 2003"

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Introduction

In December 2002, the BDI published the study „Economic Effects of the EU Substances Policy“. This study, which was performed by Arthur D. Little, ignited an intensive debate on the possible effects of the EU chemicals strategy on the economy. With this study, we highlighted the need to give more priority to the industrial policy aspects of the EU Chemicals Strategy: competitiveness and innovation. In order to achieve a lasting contribution to sustainable development, the future EU legislation in this field will have to pay more attention to the economic and to the social side of this policy.

On October 29th, 2003, the Commission of the European Communities presented its proposal “for a Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC”. This proposal comprises a series of modifications with regard to the previous Internet consultation document “Registration, Evaluation, Authorisation and Restrictions of Chemicals (REACH)” as published on May 7th, 2003, which has been assessed by Arthur D. Little in September 2003. Therefore, BDI again commissioned Arthur D. Little to identify the possible economic effects of the new proposal, using the method developed for the basic study as of December 2002, but calculating the input data on the basis of the current document.

This study was made possible by the financial support of the following federations and companies: German Building Materials Association¹, German Chemical Industry Association², German Chemical Trade Association³, Federation of the German Waste Management Industry⁴, German Association of Metal Producers⁵, The German Engineering Federation⁶, Association of Producers of Textile-, Paper-, Leather- and Fur-Auxiliaries, Surfactants, Complexing Agents, Antimicrobial Agents, Polymeric Flocculants, Cosmetic Raw Materials, Pharmaceutical Exipients and Allied products⁷, German Association of the Sugar Industry⁸ and the companies Freudenberg and BMW. We thank these institutions and the numerous experts who contributed to this study for their support.

We are confident that this study will further contribute to a constructive discussion on the economic effects of the EU substances policy and that it will provide valuable arguments for a more informed discussion on the economic effects of this important policy in the future.

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On the 29th October, the EU Commission submitted its proposal for the new EU legislation concerning the “**Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**” as developed by DG Environment and DG Enterprise, hereafter referred to as legislation proposal 10/2003. This proposal is now being discussed and further elaborated by the EU parliament. This draft shows significant changes in direct comparison to the legislation proposal published for internet consultation in May 2003, hereafter referred to as legislation proposal 5/2003.

The purpose of this supplementary study is therefore to investigate the changes within the legislation proposal 10/2003 in comparison to the legislation proposal 5/2003 and to simulate the effects on the German industry. This simulation will be done on basis of the existing calculation model specifically developed for this purpose (see Basic Report dated 18th December 2002 and the first supplementary report dated 31st August 2003 "Economic Effects of the EU Substances Policy"). All information concerning the methodology has been described and explained in this basic report so that in the following chapters only the results of the modelling are presented. In addition, qualitative differences will be elucidated and their potential effects discussed.

Effects of New Legislation Proposal on German Industry

Quantitative Evaluation

- **Overview**

The legislation draft 10/2003 contains significant relieves in comparison to the legislation proposal 5/2003. This becomes evident while comparing the results of the simulation runs with data extracted from both proposals on basis of the calculation model.

The effects for the German industry of implementing the new legislation draft are estimated as a loss of between 2.7 % to 3.3 % in gross added value, which is equivalent to a loss of between 1,000,000 to 1,230,000 jobs.

These numbers still show the strong influence of the new EU Substances Policy on the German industry. In comparison to the legislation proposal 5/2003 the burden on the German industry has been reduced by a factor of about 1.5. This has mainly been achieved by reducing the testing efforts in the low volume product range and the relevant administrative burden, as well as by the abandonment of the requirement to register polymers for the time being.

Calculation Model as published September 2003	Production loss in manufacturing industry	Gross added value loss in all industry sectors	Job losses in all industry sectors
Legislation Proposal 5/2003	14.9%	4.7%	1,735,000
Legislation Draft 10/2003 – potential know how loss	10.6%	3.3%	1,230,000
Legislation Draft 10/2003 – clear protection of know how	8.7%	2.7%	1,000,000

Tab.1: Changes in economic data due to the implementation of the new legislation proposal 10/2003

This reduction of negative effects does not reflect the fact that the information flow by the Chemical Safety Report (CSR) for the downstream user area has been waived. This burden, as described in the legislation proposal 5/2003, has not been included in the model due to its high complexity.

The main levers for the losses in gross added value and jobs are:

- Registration costs for substances
- Time loss
- Transparency of registration documents/ threat of know-how loss
- Registration costs for intermediates

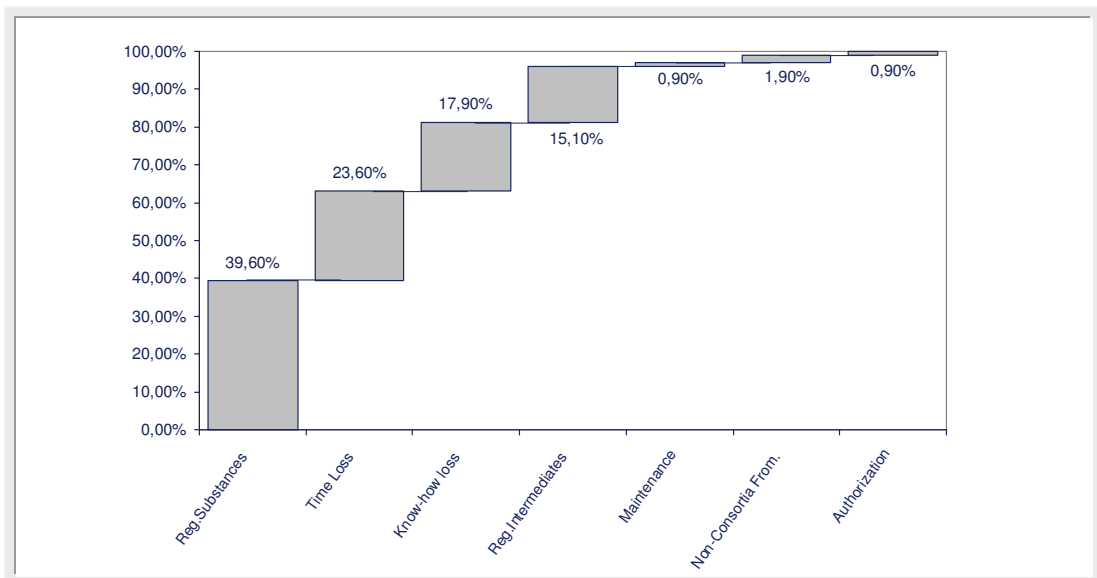


Fig.1: Influence of different levers on the total effect of the new legislation (100% is equivalent to a 3.3% loss in gross added value as calculated with the basic unmodified model)

- **Detailed Analysis**

The new legislation proposal 10/2003 has been analysed with respect to the scenario variables as described in and demanded as input for the calculation model (general reference to the basic study).

The legislation proposal 10/2003 contains significant reductions and simplifications in comparison to the legislation proposal 5/2003. The following chapters elucidate the differences in effects between the two proposals.

➤ ***Parameter Costs***

Registration costs of one substance

The registration procedure is significantly simplified for substances with low production volumes.

Production Volume 1-10 t p.a.

The testing efforts have been reduced through the omission of three tests. This departure results in a significant reduction of testing costs for each substance in the volume range 1-100 t p.a. of 28,000€:

- Cytogenicity	20,000€
- Growth inhibition algae	4,500€
- Ready biodegradability	3,500€

The exposure evaluation (5,000€) and the elaboration of a Chemical Safety Report (CSR) (5,000€) are no longer being demanded. In consequence, the research and administration efforts are simplified (5,000€ and 1,000€).

Production Volume 10-100 t p.a.

Efforts for non-dangerous substances have been reduced: exposure evaluation and risk assessment are not required anymore. A complete evaluation and assessment has to be carried out for the dangerous substances. The total reduction of efforts is assumed to reduce the average costs for exposure evaluation by 2,500€ (half of the basic value of 5,000€) and for the CSR elaboration by 2,500€ (half of the basic value of 5,000€).

The following data have been set for the simulation run (the crossed through data are those used for the simulation of the legislation proposal 5/2003).

Cost per registration of a substance incl. 5 uses in T€							
Production quantity (t p.a.)	Internal company					Official fees	Total
	Testing	Exposure	Research	Administration	Total		
1 - 10	45 17	5 0	45 5	6 5	74 27	1	72 28
10 - 100	135	45 7.5	20 17.5	16	186 176	10	196 186
100 - 1000	325	30	40	31	426	30	456

Tab.2: Costs of registration per substance

The number of the substances to be registered has not changed in comparison to the legislation proposal 5/2003.

	Production quantity (t p.a.)	Number of substances
Phase-in substances:	1-100	25,300
	100-1,000	2,500
	>1,000	2,500
Non-phase-in substances per year :	1-100	1,000
	>100	0

Tab.3: Number of substances for registration

Registration costs of one additional use

The simplifications described for the registration of substances with low production volumes are also applied to the registration of uses.

In consequence, the exposure evaluation and the CSR elaboration are omitted for the volume range 1-10 t p.a. These efforts must only be carried out for half of the uses in the volume range 10-100 t p.a.

The number of additional uses is assumed to be zero. The five uses registered within the basic registration of a substance are sufficient to cover all applications, due to the introduction of use categories.

Costs of registration per one use of a substance in T€							
Production quantity (t p.a.)	Internal company					Official fees	Total
	Testing	Exposure	Research	Administration	Total		
1 - 10	0	3 0	2 0	2.5	7.5 2.5	1	8.5 3.5
10 - 100	0	7 3.5	3 1.5	7.5	17.5 12.5	1	18.5 13.5
100 - 1000	0	12.5	5	15	32.5	1	33.5

Tab.4: Costs of registration per one use of a substance

Registration costs of intermediates

The legislation proposal 10/2003 does not differ from the assumptions set for the legislation proposal 5/2003. Therefore, the same values have also been assumed in the simulation.

Intermediates isolated on-site and intermediates isolated and transported under contract conditions are registered under the same conditions as described in the first supplementary report.

Costs of registration per one intermediate isolated on-site or transported between two sites in T€							
Production quantity (t p.a.)	Internal company					Official fees	Total
	Testing	Exposure	Research	Administration	Total		
1 - 10	10	0	2	1	13	1	14
10 - 100	10	0	3	1	14	1	15
100 - 1000	10	0	5	1	16	1	17

Tab.5: Costs of registration per one intermediate isolated on-site and intermediates isolated and transported under contract conditions

Intermediates isolated and supplied between the original supplier and recipient have to be registered under the same conditions as substances.

The total number of intermediates has been assumed to be the same as for the legislation proposal 5/2003 (data estimate by the JRC Expert Group on behalf of the European Commission).

Description	Volume range 1-100 t	Volume range 100-1,000 t	Volume range >1,000 t
Intermediates non-isolated	not given	not given	not given
Intermediates isolated and stored on-site	22,500	3,500	2,600
Intermediates isolated transported between different (more than two) sites	8,300	1,500	1,700
Intermediates isolated and supplied between the original supplier and recipient	2,500	1,100	2,200

Tab.6: Number of intermediates

Formation of consortia

The legislation proposal 10/2003 does not reveal any changes to the assumptions made for the simulation of the legislation proposal 5/2003. Therefore, the same values are assumed.

Volume range	Companies to register the substance	Cost sharing potential as % of registration costs per substance	Degree of consortia formation	Inverse Consortia Factor (ICF)	Costs of registration in total (T€ per substance)
1 - 10 t	2	60%	50%	1.7	1.7 x 28
10 - 100 t	2	60%	50%	1.7	1.7 x 186
100 – 1,000 t	4	90%	100%	1.3	1.3 x 456

Tab.7: Basic data for formation of consortia for registration

Registration costs of polymers

The legislation proposal 10/2003 does not consider the registration of polymers as the legislation proposal 5/2003 did. Therefore, the number of polymers to be registered has been set at zero.

Costs for maintaining the registration

The legislation proposal 10/2003 does not reveal any changes to the assumptions made for the simulation of the legislation proposal 5/2003. Therefore, the annual internal effort has been assumed to cost 1,000€. No external authority fee has been calculated.

Authorisation costs of substances and uses of substances

The legislation proposal 10/2003 does not reveal any changes to the assumptions made for the simulation of the legislation proposal 5/2003. Therefore, the same values have been assumed.

Cost per authorisation/authorised use of a substance in T€							Official fees	Total
Internal company					Total			
Testing	Exposure	Research	Administration					
0	50	20	80	150	125	275		

Tab.8: Cost per one authorisation or one use to be authorised

The number of additional authorisations on top of the primary one for one substance has been calculated to be 10, the same value was used for the legislation proposal 5/2003.

➤ **Parameter Time**

Time demand for non-phase-in substances

The legislation proposal 10/2003 describes the time range required by the authorities of 30 days, i.e. one month.

Production quantity (t p.a.)	Internal company					Total	Authorities	Total
	Testing	Exposure	Research	Administration				
1 - 10	4-6	1	2	1	4-6	2 1	6-8 5-7	
10 - 100	9-12	2	2	2	9-12	2 1	11-14 10-13	

Tab.9: Potential time to market losses (testing determines the time constraint, all other activities can be done in parallel)

Therefore, the intermediate value of 11 months has been assumed for the time required for the volume categories 1-10 t p.a. and 10-100 t p.a. The description of transferring the time loss into production loss has been described in detail in the basic report.

➤ ***Parameter Transparency***

The protection of confidential business information is better than before. The new legislation draft allows the formulation of one CSR for a preparation instead of requiring a single CSR for each substance/ingredient. Therefore, the know-how protection in this sensitive area is better than in the legislation proposal 5/2003. However, Art. 31 in conjunction with Annex 1 a) still requires the communication of far-reaching information regarding the components/ingredients in the preparations. Furthermore, the burden of proof concerning which information to protect is still on the company.

The calculation model allows only two options: know how loss by full transparency and full protection of know-how. An intermediate calculation is not possible. In order to have the best guess to estimate the effects, the results of both options are given.

➤ ***Parameter Authorisation***

The legislation proposal 10/2003 does not reveal any changes to the assumptions made for the simulation of the legislation proposal 5/2003. Therefore, the same assumptions have been set:

A complete ban on these very dangerous substances does not seem realistic and the effects would be difficult to determine in the model because of the specific characteristics of each individual value chain. It was therefore assumed in all our scenarios that the continued use of these very dangerous substances is ensured. It should be pointed out, however, that certain value-adding operations (e.g. doping of semi-conductors using arsenic compounds) could not be carried out without the use of these substances and therefore a complete ban on these substances would lead to a complete collapse of these value chains.

➤ ***Summary of all variables***

The following table summarises all variables given as input to the calculation model (the crossed through data are those used for simulation of the legislation proposal 5/2003).

Parameter	Scenario variable	Production Volume p.a.	Unit	Legislation Proposal
Costs	Costs of registration per substance incl. 5 uses	1-100t	€/kg	20,3 8.7
		100-1,000t		1.5
		>1,000t		negligible
	Number substances to be registered as phase-in	1-100t	-/Europe	25,300
		100t-1,000t		2,500
		>1000t		2,500
	Number substances to be registered as non-phase-in	1-100t	-/Europe p.a.	1,000
		100t-1,000t		0
		>1,000t		0
	Costs of registration per substance for additional use	1-100t	€/kg	2.4 1.0
		100-1,000t		0.1
		>1,000t		negligible
	Number of additional use registrations above the 5 uses in the basic registration	all	1/substance	3 0
	Inverse consortia factor (Number of basic registrations)	1-100t	1/substance	1.7
		>100t		1.3
	Number of intermediates isolated (type 2 and 3)	1-100t	-/Europe	30,800
		100t-1,000t		5,000
		>1,000t		4,300
	Number of intermediates traded (type 4)	1-100t	-/Europe	2,500
		100t-1,000t		1,100
		>1000t		2,200
	Costs of registration per intermediate (type 2 and 3)	1-100t	€/kg	3.8
		100t-1,000t		0.1
		>1,000t		negligible
	Number of polymers for relevance analysis	all	-/Europe	400,000 0
	Costs of relevance analysis	all	€/polymer	irrelevant
	Number of polymers to be registered as Phase-in	1-100t	-/Europe	166,997 0
		100t-1,000t		16,502 0
		>1000t		16,502 0
	Costs of registration per polymer	1-100t	€/kg	irrelevant
		100t-1,000t		Irrelevant
		>1,000t		Irrelevant
	Number of polymers to be registered as Non-Phase-in	1-100t	-/Europe p.a.	16,700 0
		100t-1,000t		1,650 0
		>1,000t		1,650 0
	Authorisation costs (including authorisation of uses)		€/substance	275,000

Parameter	Scenario variable	Production Volume p.a.	Unit	Legislation Proposal
Costs (ctd)	Multiple authorisations per substance		1/substance	10
	Payback period for costs for Phase-in registration		Years	7
	Annual maintenance costs per registration or authorisation		€ / registration and year	1,000
Time	Time lost in registration of substances	1-100t	Months	± 11
		>100t		not relevant (no new substances in this volume range, see bases)
Duty of authorisation	Details of substance restrictions	all	-	without restriction
Transparency	Details of transparency regulations	all		Know-how loss through disclosure determined by third parties, i.e. cannot be influenced by industry or Full know-how protection as degree of information can be influenced by industry

Tab.10: Summary of data fed forming the basis for the simulation

Qualitative Evaluation

• **Overview**

The analysis shows several changes to be discussed by comparing the proposal 10/2003 and the proposal 5/2003:

- | | |
|--------------------------|---|
| - Duty of Care | Term left out |
| - Phase-in Substances | Definition broadened |
| - Monomers | No intermediate, registration necessary |
| - Information Transfer | Free transfer of data after 10 years |
| - Cost Sharing | Equal shares of costs for all registrants |
| - Safety Data Sheet | All relevant chemical safety assessment appropriate |
| - Downstream Users | Relieves in information transfer |
| - Chemical Safety Report | Review of procedure in 12 years |

These changes between the proposal 10/2003 and the draft 5/2003 induce overall relieves for the industries, i.e. Chemical industry and the downstream users. Recognised concerns from the internet consultation phase such as Duty of Care have been considered and adapted.

Some changes bring additional burdens such as the registration of monomers. But these burdens are the consequences of other relieves.

• **Detailed Analysis**

The identified changes are described and the potential effects on the German industry are developed in the following chapter

Duty of Care:

Issue	Article (Proposal 10/2003)	Proposal 10/2003
Duty of care	1 and others	Not used anymore

The dismissal of the term “Duty of Care” is of major relevance. In the internet consultation industry feared that the duty of care would expose them to unlimited liability claims. In consequence the term “Duty of Care” has now been left out in the final proposal.

This change takes away a major concern of the industry as stated in the internet consultation.

Phase-in substances:

Issue	Article / Page (Proposal 10/2003)	Proposal 10/2003
Phase-in substances	Definition / 70	Substances over 15 years preceding the entry into force of the Regulation
		it was manufactured in or imported into the Community,....., by a manufacturer or importer and....

The definition of the phase-in substances has been broadened by changing two major issues:

Now, the rule of phase-in substances becomes relevant for all companies if the condition for a phase-in substance has been once fulfilled by any manufacturer/importer in the Community.

The time frame during which the substance has had to be produced within the Community has been enlarged by 5 years up to 15 years.

Both changes allow more companies to participate in the relieves of the phase-in substances as well as potentially a larger number of phase-in substances.

Monomers:

Issue	Article / Page (Proposal 10/2003)	Proposal 10/2003
Monomers	5 / 20	Monomers have to be registered ...even they are used as intermediates, and it is declared that the lighter rules on intermediates are not subject to registration

The explicit inclusion of monomers into the registration process is the consequence of the exclusion of the polymers from the REACH process.

The change will increase the burden of the industry because most monomers are only used as intermediates. The detailed analysis being necessary to make a quantitative analysis would break the frame of this supplementary work.

Information Transfer

Issue	Article / Page (Proposal 10/2003)	Proposal 10/2003
Information transfer	23 / 25	.. to make data that have been in the possession of the Agency for at least 10 years, freely available to others for the purposes of registration

The new proposal 10/2003 stresses the period of 10 years during which the cost sharing procedure is fixed. After this time frame, the agency will be allowed to share the data freely for further registration processes.

Cost Sharing

Issue	Article / Page (Proposal 10/2003)	Proposal 10/2003
Cost Sharing	25 / 25	...equal share

The new proposal stresses the equal portion for every company participating in the cost sharing process, i.e. the balance of burden is given.

This change avoids for the 2nd or 3rd registrant a too high cost burden in comparison to the 1st registrant and therefore unequal competitive conditions.

Safety Data Sheet

Issue	Article / Page (Proposal 10/2003)	Proposal 10/2003
Safety Data Sheet (SDS)	29 / 26will be extended by the requirement to convey information from any relevant chemical safety assessment

The new proposal describes the expansion of the Safety Data Sheet. This expansion bases mainly on giving up the Chemical Safety Report for substances in small volumes. The use of any relevant chemical safety assessment is allowed, i.e. the chemical safety assessment has not to be done by the originator of the SDS.

Downstream Users

Issue	Article / Page (Proposal 10/2003)	Proposal 10/2003
Downstream users	34 / 27	However, downstream users need not prepare a chemical safety report: <ul style="list-style-type: none"> - If they take more thorough risk management measures than.... - for non hazardous substances - in cases where their supplier would not have had to prepare a chemical safety report
	35 / 28	Downstream users do not have to report if they are using a substance in quantities of less than 1 tonne

The constraints for preparing a Chemical Safety Report have been relieved for the downstream users by the new proposal.

This change follows the major concerns within the internet consultation that especially small and mid-sized downstream users will be burdened by the reporting procedure.

Chemical Safety Report

Issue	Article / Page (Proposal 10/2003)	Proposal 10/2003
CSR	133 / 50	Review of process 12 years after the Regulation enters into force

The review of the described legislative processes will be allowed 12 years after entering into force.

This allowance might lead to significant changes after the set time frame and in consequence to a situation of uncertainty.