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Research Paper

Testing Costs and Testing Capacity According to the REACH Requirements – Results of a Survey of Independent and Corporate GLP Laboratories in the EU and Switzerland

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Abstract: This study focuses on the prices for laboratory testing services and testing capacity in nine of the major European chemicals producing countries. The purpose is to bridge the existing gap of a representative study on test prices and the available testing capacity. At the core are seventy-six test categories, in particular toxicological and ecotoxicological tests as required by REACH, the EU Chemicals Policy Review. The price and capacity information was gathered by a survey of twenty-eight independent and corporate laboratories in the second half of 2004. The survey aimed at finding out minimum, average and maximum estimates of costs/prices and the available average and maximum testing capacities. The data exploration has shown a considerable variability in the prices for single tests. For reasons of completeness an overview of the testing cost for a registration according to the four work packages of REACH is provided. The most difficult issue was the estimation of average and maximum testing capacities. Surprisingly the large laboratories supply with 96.5% the vast amount of the total capacity available for testing chemicals in the nine European countries the survey has covered. A complete set of tables and figures representing detailed price and capacity information is available upon e-mail request to the author.

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Introduction

An effective system of chemicals control in the EU calls for very detailed information. Although a number of surveys is available no representative and detailed survey on testing cost as required according to the REACH proposal is at hand. Neither is there a survey on the available testing capacity in the EU. The most recent study on testing cost was published in August 2004 by BAuA--the Notification Unit according to the Chemicals Act at the Federal Institute for Occupational Safety and Health in Germany [1]. Their survey is based on the requirements for the notification of new chemical substances. The notification of new chemical substances in the EU requires specific test data to be provided by the notifier of the new substance. The testing requirements depend on the volume of the substance marketed per annum. The EU regulation distinguished three main categories, that is the "Base Set" of information, "Level 1" data, and "Level 2" data [2]. BAuA has tried to determine the testing cost for these three categories. However, it does not cover the complete set of test as required by the REACH proposal, which can be seen in appendix 1. A current overview of studies on testing costs is provided in a study of the German Federal Environmental Agency [3].

This study is to bridge the gap of a representative study on test prices and the available testing capacity. The study seeks to establish a statistical basis for a standard price for the single tests as specified in the REACH proposal by exploring the existing price variability. For the testing laboratories offering their services to a broader market, it is the net price charged to their customers. And, for the company labs, the standard price is a market-oriented transfer price, which they would charge to their internal and external customers. Thus, this price comprises more than the actual or standard costs of a test. It includes all costs associated with the carrying out of a test, including rent, overhead, and centrally funded costs, as well as a profit margin. Thus, this price is a good indicator of the single market price for corporate laboratory services.

This study covers the tests as specified by the European Commission in their REACH proposal Appendix IV to VIII, dated 29 October 2003 [4]. In several cases the original REACH testing requirements are not specific. Therefore, we consulted a paper by Pedersen et al. [5] and experts from the testing laboratories, as well as the current literature [6]. This survey focuses on 28 laboratories and chemical companies in Austria, Belgium, Denmark, France, Germany, Italy, the Netherlands, Switzerland and the UK.

In the next section of the article we briefly discuss a few methodological issues and describe the design of the study. The questionnaire and the sampling procedure is described in detail. In section three the results are presented and discussed. We focus on the variability of prices and its causes and the difficulty of quantifying the available testing capacity. Section four summarizes the major findings.

Method and data

Methodological considerations

We should start with a theoretical remark about market prices. The remark is based on microeconomic theory [7]. From a microeconomic viewpoint the price in a competitive market is given, as is the capacity. The market price is the price at which demand matches supply. The market for laboratory testing services can be regarded as a perfectly competitive market since it has many buyers and sellers, so that no single buyer or seller has a significant impact on price. In a perfectly competitive market a single market price will usually prevail. In case the market is not perfectly competitive different laboratories might charge different prices for the same test. This can happen when one laboratory is trying to win customers from its competitors, or because customers have loyalties to laboratories, in which case these laboratories can charge higher prices than their competitors.

Market prices are only revealed as the result of market transactions. For our study this implies checking market transactions regarding laboratory-testing services for the past several years. This procedural consideration was put aside during the pilot phase of the study because the laboratories could not afford to check for a representative sample of past market transactions in order to derive prices. The only way forward was to focus

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on the prices they would charge for their testing services. And, it is reasonable to assume that the prices for specific laboratory tests will be a good indicator for the market price.

Capacity for testing services is a subtle thing. Usually, for most products, long-run supply is much more price elastic than short-run supply. This because firms face capacity constraints in the short run and need time for capacity expansion, for example by building new testing facilities and hiring qualified staff. It could be that short-run capacity rises if prices rise sharply. The available capacity is based on the cost function of the specific laboratory for single tests and on the relationship to the market price. Such a cost function is a relationship itself between the cost of conducting such tests and the output of a laboratory. An important issue is how the structural factors of a laboratory affect this relationship.

Estimating the available capacity for testing services is difficult and one that is pivotal to the survey. Capacity is difficult to quantify for many reasons. Nearly all laboratories – be they independent or corporate laboratories – provide services to several industry sectors. Thus, only the total capacity available could be given. Estimation of capacity is further complicated by the large diversity of studies the laboratories offer.

Study design and data collection

The study was designed as a cross-sectional survey using a questionnaire. We focused on the EU countries with a large share of chemicals manufacturing volume and on Switzerland because this allowed the study to cover most of the independent and corporate laboratories in Europe. Therefore the study could produce representative results and remain manageable.

The questionnaire covered five major areas. The first column of the questionnaire included the numbering of the Appendix of the REACH proposal so that the tests were grouped according to their subject (see appendix 1). Under the column, "Test guidelines", the OECD and EC test guidelines were also quoted. Again, it should be mentioned that REACH is not specific in all cases.

The questionnaire included the following sections:

- General questions about the company/laboratory
- Identification of the substance/ Information on manufacture and use of the substance (3 items)
- Physical-chemical tests (16 items)
- Toxicological tests (28 items)
- Ecotoxicological tests (28 items)

The survey aimed at finding out minimum, average and maximum estimates of costs/prices, which were based on costs/prices of the past two years. Although one might doubt averages, they do reflect a "sensed" underlying distribution. Several factors are influencing the distribution. Among others these are the properties of the substances to be tested, unexpected events during the tests, and intermediate results; because they often determine the effort and inputs for single tests; and as such the costs/prices of these. That is the exact actual costs/prices could only be given when details on the substance to be tested are known by the laboratory. Moreover, the prices for the single tests do not include costs for dose range finding and for the development of analytical method.

The capacity to conduct testing as required by the REACH proposal is available from both the chemical firms and independent testing laboratories. The required tests need to be conducted in general according to the Principles of Good Laboratory Practice (GLP) first published by the OECD in 1982 and revised in 1997 [8]. This meant for our survey that all prices/costs needed to be based on GLP requirements. GLP is a quality system covering the organisational process and the conditions under which non-clinical safety and environmental studies are planned, performed, monitored, recorded, reported and archived.

The following nine categories show the areas of expertise in which laboratories might choose to specialise. The category numbers correspond to the official GLP numbering of these fields.

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1. Physical-chemical testing

   These tests measure physical and chemical properties of substances like melting point, flammability etc.

2. Toxicity studies

   These studies assume that tests on animals can be used to evaluate the toxicity effects on humans. Examples are acute toxicity studies (oral, dermal, inhalation) and carcinogenicity studies.

3. Mutagenicity studies

   These are studies to explore the gene toxicity of substances, for example gene mutation studies like the Ames test.

4. Environmental toxicity studies on aquatic and terrestrial organisms

   Examples are short-term acute toxicity studies on daphnia.

5. Studies on behaviour in water, soil and air; bioaccumulation and metabolisation

   These studies explore whether and how substances remain in the environment. Examples are biodegradability and bioaccumulation studies.

6. Residue studies

   They are mainly applied to pesticides. Tests are made for all types of agricultural crops (from corn to hops, fruits and vegetables) as well as long-term soil degradation studies.

7. Studies on effects on mesocosms and natural ecosystems

   These are very specific studies for pesticides like Pond studies. Artificial ponds are used to test different concentrations of substances.

8. Analytical and clinical chemistry testing

   This is a special category to characterize laboratories which provide only the analytical part of testing services from categories 2 to 7. They are dealing mainly with biological materials.

9. Other studies

The compliance monitoring is organised at the national level. The responsible national agencies report on the monitoring results to the OECD GLP Office and to the corresponding office at the EU Commission.

The recent lists of GLP laboratories for the year 2003 mention that Germany has 159 laboratories, the UK 128, France and Switzerland 44 each, the Netherlands 36, and Italy 29. These lists include independent labs and corporate labs, which all conduct their testing in compliance with the GLP Principles.

We have used the lists of the GLP laboratories with their areas of expertise to define the parent populations to be considered. Besides the eight areas of specialization listed above there are certain industry-specific specializations. The products and industries the labs are specialized in include chemicals, pharmaceuticals, agrochemicals, food, biocides and environmental legislation. Thus we had to select on a case by case basis those laboratories specialized in testing chemicals. Based on our knowledge and the knowledge of experts we tried to identify all relevant testing capacity for chemicals in the surveyed countries. However, the approach remains arbitrary, mainly due to a lack of more detailed information on the sampled population. A disadvantage of this procedure is, that it makes no sense to calculate a response rate because of the necessary but judgemental selection procedure.

We discussed the issue and the criteria which laboratories to include in the survey with experts, in particular with the British and German GLP Offices. Several laboratories were easily dropped according to their name, which suggested a business other than chemicals testing. More important was a systematic screening of the indicated areas of expertise of the GLP laboratories. We could exclude the areas 6) residue studies, 7) mesocosms and natural ecosystem, 8) clinical chemistry (applied for the pharmaceutical industry) and 9) other studies. We contacted the remaining GLP laboratories by phone and asked whether they would like to participate in the CEFIC survey. The result was that 51 laboratories showed their interest in participating in the survey (see table 1). In the end twenty-eight of these laboratories responded, of which we could use twenty-six in our analysis.

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Country	All labs		Participating labs		All participating labs	
	Independent Labs	Corporate Labs	Independent Labs	Corporate Labs	Number	Percent
Germany	14	5	9	2	11	39.3
United Kingdom	7	6	4	0	4	14.3
France	4	1	3	1	4	14.3
Netherlands	2	2	2	1	3	10.7
Italy	3	0	2	0	2	7.1
Austria	1	0	1	0	1	3.6
Belgium	1	1	1	0	1	3.6
Denmark	1	0	1	0	1	3.6
Switzerland	1	2	1	0	1	3.6
Total	34	17	24	4	28	100.0

Table 1: Sample of independent and corporate laboratories involved in the survey

The prices and capacity we asked for were from 30 June 2004. The author conducted the survey from August to December 2004. This long survey period has to do with the interest in including as many laboratories as possible. It also took a lot of effort for the laboratories to compile the requested information. We should mention that all of the large independent laboratories from the nine participating countries are included, with the exception of one.

We should also mention that there are only a few corporate labs remaining in existence; in fact we obtained data from only four corporate laboratories. There is an ongoing process – but seemingly terminated – of phasing-out corporate laboratories for toxicological and ecotoxicological testing (and also for physical-chemical testing). The process could be observed in all the participating countries, with the result that few corporate labs remain. If we take a representative sample of seventeen large European firms which are listed in the global top fifty chemical companies in 2004 [9] than only four of them still have their own significant testing facilities.

A separate issue is, that the relative number of participating corporate labs is considerably lower than that of independent labs. This is due to the fact, that corporate labs are mainly managing regulatory compliance issues using independent labs for testing services. These corporate labs belong to large chemical firms which keep nevertheless the GLP status for their labs, but do not provide extensive testing services. This was the main reason for them not to participate in our survey.

Results and discussion

Summary of data and analytic technique

The data exploration has shown a considerable variability in the prices for single tests. Three attempts were made to reduce the price variability of the sample. The attempts were based on the response pattern to the three requested prices. The responses show the following pattern of prices given:

- Average price
- Average, minimum and maximum price
- Minimum and maximum price (price range)
- Minimum price

The first and the second responses posed no problem for calculating the mean and median of the average price. However, the laboratories have sometimes chosen for the same reason a different response pattern. In cases of a broad range of prices for a particular test category some preferred

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to give minimum and maximum prices only whereas others preferred to give the average price instead. The problem was that about a third of the respondents gave only the price range or the minimum price. This information would be lost in a rigid calculation of the mean and median of the average price since these respondents would not enter in the estimation of the statistical parameters. Thus, three options were considered to substitute the missing average price: first to use the minimum price; second, to use the mean of the minimum and the maximum price; and third, to use both of these substitutes.

The reasons not to use these substitutions are the same that underlie the respondents' behaviour. The main reason is that there is a strong impact on testing costs related to the characteristics of the substance to be tested. For a number of tests then, no normal average price can be given. In these cases only a price range is meaningful. However, this depends on the substances a laboratory usually tests. And in effect, as the responses show, for some labs an average price is still meaningful, whereas for others only a price range or a minimum price can be determined.

We have experimented with all three approaches to substitute for the missing average price. In the end, however, we found no less price variability than analysing the original data with a number of average prices missing.

Due to the comparatively small sample size and to reasons of comparability we limited the following presentation and discussion of the single tests to mean and median values.

Analysis of prices

An overview of minimum, average and maximum prices:

Appendix 1 offers an overview of the means of the average prices for the single test categories. It also shows the number of laboratories that provided data on average prices. For the purpose of comparison we included the costs as surveyed by BAuA [1].

Test categories	Min. price	Max. price	Avg. price			
	Mean	Mean	Median	Mean	CV (%)	Ratio mean to median
v 014 - Development of analytical method	4,567	8,333	2,250	5,239	100	2.3
vii 5.20 - Viscosity	891	983	600	860	49	1.4
vi 6.8.1 - Assessment of toxicokinetic behaviour	25,818	74,803	1,823	33,041	218	18.1
v 7.1.1 - Short-term acute toxicity study on daphnia	3,386	6,135	3,500	3,742	53	1.1
v 7.1.3 - Short-term acute toxicity study on fish	3,949	7,336	3,500	4,193	58	1.2
vii 7.1.6.1 - Fish early-life stage (FELS) toxicity test	28,717	47,839	21,000	26,254	60	1.3
vi 7.3.1 - Adsorption/desorption sceening study(HPLC method)	3,521	2,980	2,600	3,878	96	1.5
vii 7.3.2 - Bioconcentration in (one) aquatic species,preferably fish	43,873	87,082	28,250	40,333	96	1.4
vii 7.4.2 - Effects on soil micro-organisms	10,311	7,513	6,913	11,765	81	1.7

Table 2: Selection of test categories with high price variability

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Price variability and its causes:

We have measured price variability using two statistical parameters--the coefficient of variation and the ratio mean to median prices.

The coefficient of variation expresses the standard deviation as a percentage of the sample mean. This is useful because we are interested in the size of the variation relative to the size of the observation. Thus, we can compare the variability of a test price with a mean of 800 Euros to one of 80,000 Euros. The standard deviation alone would not allow for this possibility. Furthermore, the coefficient of variation is fairly easily understood and it incorporates all the relevant data. However, there is no general standard for an acceptable level of price variability. Thus, we had to fix a reasonable boundary.

The ratio mean to median of a sample of observations is a crude measure of the amount of variability (dispersion) in the distribution of the sample. It is commonly used to measure the skew of a distribution. And it is a simple way of identifying the test categories with the greatest variability in prices. A step-by-step screening has led to nine test categories with high price variability. Table 2 summarizes the statistical properties of these tests.

The table shows one extreme outlier in the test category "Assessment of toxicokinetic behaviour (vi 6.8.1)". Out of the six responding laboratories four gave a very low price, one lab gave 7-times the median of the average price and the outlier lab 100-times the median of the average price. One possible reason for the majority of prices around 1,800 Euro might have to do with the actual legal requirements. In the OECD-Guideline 417 respective EU-Guideline B.36 expensive experimental testing is applied for a production volume beginning with 100 tonnes per annum. However the REACH proposal has lowered this boundary to 10 tonnes per annum. Thus, the majority of the labs might not have considered changes in the REACH testing requirements.

The outlier sheds as well light on three factors, which may have caused the variability of the prices. First, the prices may not reflect identical test offers, that is the products are not homogeneous and thus no single market price is able to prevail. This possibility could not be avoided in our survey because we could not ask for data covering the whole set of 30,000 chemical substances involved. Second, there are economic reasons, which include differences in input factors, efficiency of the laboratories, product portfolio and size, etc. Third, there is a miscellaneous category of reasons, such as differences in physical locations, that is when geographical differences are likely to lead to structural differences. E.g. laboratories which are located in areas heavily concentrated with firms of the chemical industry might have different demands for their testing services than laboratories in less concentrated areas. We discuss how these factors might have influenced the established price variability immediately below. An example of a test category with high price variability is "the acute toxicity study on daphnia". Figure 1 shows the distribution of average prices as a histogram. This test uses daphnia which are small crustaceans, about 0.2 to 5 mm in length. They are used because they exhibit consistent responses to toxins in water. They are simple to be produced in large number. However, there are differences to do this as well as in the application of the experimental testing design. Figure 1 shows these differences and shows a price advantage of the small labs. The most obvious reason for price variability is that the properties of the specific test categories as outlined in our questionnaire were not perceived as unambiguous. The test categories left room for interpretation and diversity. The nine test categories in Table 2 illustrate that the prices surveyed may include different testing methods and services. We have tried to avoid this systematic bias by indicating the respective OECD and EU testing guidelines in the questionnaire. However, the testing guidelines themselves include a variety of testing options, which have implications on the cost of the overall test to be undertaken for a specific substance.

We should now consider the second reason for price variability, which has to do with economic factors. Among the few important economic determinants of cost are: size of the laboratory, prices of input factors (labour and materials), rate of output (i.e., utilization of fixed laboratory personnel and equipment), quality of input factors, size of the testing lots, laboratory technology, and the organization of the laboratory. One determinant on which we have information is the

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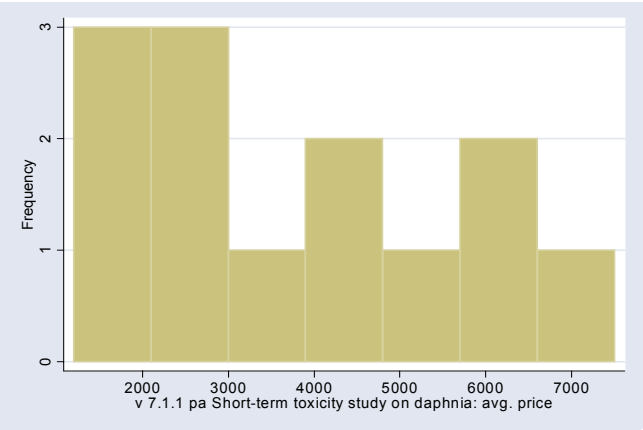

V 7.1.1 – Acute toxicity study on daphnia		
Type of lab	N	Avg. price: Mean in Euros
All labs	13	3,742
Small labs	5	2,330
Large labs	4	4,900
Corporate labs	4	4,350

Figure 1: Analysis of a test category with high price variability

size of the laboratories. Our sample size is not large enough to test for differences in price means. We can, however, take a look at the actual differences in prices subdivided by size-classes. And a size-class distribution, which divides our sample well, is if we define "small labs" as having 1 to 100 employees and "large labs" as having more than 100.

We have tested for the difference in the means of the average price using only the small and large labs. We applied a Mann-Whitney U-test for the average price of 76 tests. In one case (1.3%) no lab offered the test and in eight cases small labs did not offer the tests (10.5%). In five cases (6.6%) we found a significant statistical difference in the averages prices between small and large labs at a 5%-level of significance. However, for the large majority of test categories, that is for 62 cases (81.6%) we found no significant statistical difference at the 5%-level in the in the price offered by small and large labs.

There are three points that we should mention. First, the small labs are not really that small. They average thirty-one employees. In comparison, the large labs average 386 employees (if we exclude one very large lab). The size of the small labs might be related to comparative advantage. E.g. the price advantages of the small labs might be due to advantages of specialization. Small labs generally offer a limited package of tests, which might enable them not to incur high fixed-costs. Second, we have no indication that the small labs have responded strategically, that is that they have responded to us with lower prices then they usually would charge. Third, the small labs supply on average only 3.5% of the overall capacity for testing services, for two thirds of the required tests the large labs supply the entire testing capacity. Due to this fact we have not explicitly included the mean values of the small labs into the estimation of testing costs for work packages according to REACH. However, they are implicitly included because we use the mean values for "All labs", which the small labs have a strong impact on.

Estimation of testing costs for work packages:

For reasons of completeness we provide an overview of the testing cost for a registration according to the four work packages of REACH. The estimation used the mean values of the average and maximum prices for the single tests. The test categories are specified in the Appendix V to VIII of the REACH proposal of October 2003. The estimated test costs can be adjusted for special cases. We have added an estimated amount of costs for the development of analytical methods for the single work packages. The amounts are 20,000 Euros for 10-100t/y, 40,000 Euros for 100-1000t/y and 50,000 for >1000 t/y. It should be mentioned that the cost for the development of analytical method can vary enormously. The important point is, that our survey provides a very detailed and reliable source for actual prices for GLP testing services.

For our estimation of package prices we used, so to speak, three scenarios. First, the mean value of average prices of all labs and second, the one for the large labs. The former provides the low price level due to the relative low prices of the small labs it includes. The third scenario is based on the mean value of the maximum prices of all labs. The reason that in case of work package "100-1000 t/y" the maximum price is lower than the average price is that both price means include

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partly different labs with a different response pattern.

Analysis of capacity

Difficulty in quantifying capacity:

Laboratories which could perform the tests as specified in the REACH proposal belong to subgroups of the main group "74.30 Technical testing" of the European classification of economic activities, NACE. The subgroups are:

- 74.30.1 Engineering control and analysis,
- 74.30.2 Physical testing and analysis and
- 74.30.3 Chemical testing and analysis.

However, most of the Statistical Offices of the European Member States have only recently begun to collect information on this service sector, and they provide – if at all – only data for the main group 74.30.

To our knowledge and based on data downloaded from the Eurostat database in February 2005 we can conclude that statistical data on employment, cost, sales and the size distribution of laboratories since the year 2000 is only available for Germany and Italy for NACE 74.30. Thus, we cannot use official statistics for the purposes of our study. Furthermore, this data is too unspecific for estimating the available capacity for single tests. At best it could give a clue to make a guess about the overall laboratory capacity in the EU.

We have sampled the laboratories for participation in this survey based on whether they perform testing according to GLP. This basis for the sampling of the laboratories has led to a quite representative picture of the overall testing capacity for industrial chemicals. This is because all of the large laboratories have responded to our questionnaire, except one lab in the UK, which primarily conducts pre-clinical studies for the pharmaceutical industry. Nearly all of the medium-sized and small labs – from Belgium, France, Germany, Italy and the Netherlands – which provide testing services for the chemical industry are included.

Note that only very few of the labs with GLP status work for the chemical industry. We estimate that the share is less than 10%. Furthermore, we have included nearly all of the corporate labs. As already mentioned there are very few corporate laboratories left. The capacity estimation and questions we asked the laboratories were based on the following considerations.

Laboratory capacity is the capability to perform tests according to professional standards or guidelines. From an economic perspective the capacity of a laboratory for testing chemical substances represents the rate of operation that will yield the minimum average total cost of tests. Capacity in this sense is not fixed, but will vary with changes in the costs of the factors of conducting the tests. Capacity can be regarded as being optimal when a situation is achieved at which cost per unit of test is minimized.

The estimations of average and maximum testing capacities are still very difficult because they depend on a number of boundary conditions which impact on capacity management. It is particularly difficult for large laboratories with high capacity, which provide services to a number of industry sectors. Capacity is further complicated by the large diversity of studies they offer.

It is important to recognize that the maximum number of test per annum is the total theoretical capacity of a laboratory for each single test/study

	1-10 t/y	10-100 t/y	100-1000 t/y	>1000 t/y
Average price, all labs	56,360	279,838	799,562	1,582,616
Average price, large labs	70,407	292,269	916,340	1,610,910
Maximum price, all labs	81,120	409,602	872,724	1,966,189

Table 3: Summary of the estimated test costs for work packages of REACH Appendix V-VIII (in Euros per substance)

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Required test package	Range of annual volume in tonne/year	Share of the total number of substances (%)	No. of required test packages based on 282 substances p.a.	
			EU capacity (excl. an import share of 53%)	EU capacity and Switzerland
Base set	1-10	57.8	77	98
Level 1a	10-100	8.5	11	14
Level 1b	100-1000	2.9	4	5
Level 2	>1000	0.6	1	1

Table 4: Estimation of the annual overall testing capacity according to the test packages for the notification of new chemical substances

type considering no other studies in the same category. Hence, the actual number of studies conducted – that is the average testing capacity – does not reach the maximum number but depends on the number of other tests of the same category and may vary considerably from year to year.

Laboratory management might imply short-term shifting of capacity from one test category to another or from one department to another; however, it does not increase capacity itself. We estimate that about one-half of the laboratory capacity might be shifted during short-term capacity adjustment.

For all these reasons, we have asked the labs to consider an estimation of the average and maximum number of tests based on the number of tests that they are able to conduct per year, as well as the number of tests they conducted in the past one or two years. The critical question certainly concerns the average capacity since this knowledge is needed to determine the number of studies the labs could reasonably run

No. of REACH appendix and test category	No. of labs	Total avg. capacity
viii 7.4.5 - Long-term toxicity testing on soil invertebrates	2	6
viii 7.6 - Long-term or reproductive toxicity to birds:	3	9
vi 6.7.2 - Developmental toxicity study (rabbits), oral gavage	3	12
vii 7.2.1.4 - Sediment simulation testing (for substances adsorbing to sediment)	6	12
viii 7.4.6 - Long-term toxicity testing on plants	2	12
viii 7.4.4 - Long-term toxicity testing on earthworms	7	16
vii 7.3.2 - Bioconcentration in (one) aquatic species, preferably fish	8	19
vii 7.4.2 - Effects on soil micro-organisms	7	19
vi 6.6.1b - Short-term repeated dose tox.: 28 days, inhalation (rats)	8	21
viii 6.6.3 - Long-term repeated dose tox. study (longer than 12 month)	10	21
vii 7.4.3 - Short-term toxicity testing on plants	6	25
vi 6.4.2 - In vitro cytogenicity study in mammalian cells (MNT)	3	28
vii 6.7.3 - Two-generation reproduction tox. study, oral gavage	11	28
viii 6.9 - Carcinogenicity study (rats)	11	29
vii 7.2.1.3 - Soil simulation testing (for substances adsorbing to soil)	7	29
viii 7.5 - Long-term toxicity testing on sediment organisms	6	30

Table 5: The 16 test categories with the lowest average annual test capacity in the major European chemicals producing countries

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simultaneously over the course of one year. Furthermore, the labs need to be able to provide analytical backup for all these studies at the same speed as the in vivo part of the study and their capacity to do this currently would depend on the availability of the methods and the ease of set up.

Estimation of testing capacity:

To estimate the available testing capacity we used the information collected with our survey on average and maximum capacity. We estimated the overall capacity for the tests as required by REACH by totalling all the capacities of the individual laboratories. The information was collected for each test category, so that we could draw a very detailed picture concerning the overall capacity for single tests for the nine countries we have surveyed.

The data on the number of notifications of new chemical substances and their structural composition may be regarded as one proxy for the overall capacity in the EU for the testing of industrial chemicals. From the Website of the ECB, the European Chemicals Bureau in Ispra [10], we received the following statistical information summarized in Table 4.

Since 1994, an annual average of 282 new chemical substances has been notified. This average is based on the total number of new chemical substances. It includes imported chemicals to be notified, particularly from the USA (22%), Japan (18%) and Switzerland (13%). From the overall average of 282 substances we can attribute 47% to the testing capacity in the EU. For the EU and Switzerland this would be a share of 60%.

This number of test packages to be performed annually is obviously a lower bound and compared to our capacity figures very low. We have summarized the average and maximum testing capacity in appendix 2. The ratio of the maximum capacity to the average capacity available is about 2.5. Again, this indicates that the average capacity is a good indicator for the available testing capacity in the major European chemicals producing countries since it is reasonably lower than the surveyed maximum capacity. Appendix 2 also shows the average capacity for small and large labs. The maximum capacity is given for all labs.

A final consideration regarding available capacity should be stated. This has to do with the question of whether there might be severe bottlenecks for certain testing services. If we order the test categories beginning with the lowest average annual testing capacity we obtain the following picture.

Among these sixteen test categories with an average capacity of thirty or less tests per annum are three which already belong to the REACH Appendix VI testing package for 10-100 t/y, that is, where a considerable number would have to be undertaken if the REACH proposal would come into force. Six test categories belong to Appendix VII (100-1000 t/y) and seven to Appendix VIII with more than 1000 p.a. It is obvious that the actual testing capacity would become a bottleneck when REACH is implemented.

Conclusion

This study provides a contribution to the empirical foundation of the variability of prices for laboratory testing services. The analysis emphasizes many important questions related to competition in this segment of the service sector. In addition, statistical information is provided on the supply side of this sector, that is, information on the testing capacity in nine of the major European chemicals producing countries is given. Below is a very short summary of the major results and suggestions for further study.

1. The data exploration has shown a considerable variability in the prices for single tests and the impact of three factors causing this variability.
2. The first factor that has caused this variability is that the properties of the specific test categories as outlined in our questionnaire were not perceived as unambiguous.
3. The second factor is a bundle of economic determinants including differences in input factors and the size of the laboratories. A surprising result is that laboratories with 100 or less employees provide their testing services at a lower price level. However, this result is statistically not significant. It seems to be that small laboratories can

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already achieve economies of scale in providing testing services by specialising in a limited portfolio of test categories. The large laboratories instead have to carry a substantial burden of fixed-cost due to their full-range testing portfolio.

4. In order to be complete an overview of the testing cost for registration according to the four work packages of REACH is given in Table 3.
5. The most difficult issue was the estimation of average and maximum testing capacities since they depend on a number of important factors, particularly on the portfolio of the offered and ongoing tests. Nevertheless, data on the available capacity for the testing of industrial chemicals is provided.
6. The large laboratories (defined as laboratories with more than 100 employees) supply 96.5% of the total capacity available for testing chemicals in the nine European countries the survey has covered.

For further study four suggestions should be considered. First, to increase the understanding of competition in this part of the service sector, particularly the understanding of the price variability and capacity supply by GLP laboratories, it is necessary to go into much more detail concerning the cost structure and the determinants of testing cost. This would imply considerably increasing the number of test categories over the seventy-six that we have used. Second, the range of testing cost is partly determined by the properties of the chemical substance to be tested. If a typology of substances could be developed to allow the clustering of chemicals according to testing relevant properties, then cost functions for testing cost could be constructed to derive more precise testing cost estimations. Third, the same applies to the development of analytical methods to be able to conduct the tests. Finally, the EU needs to further develop is official statistics covering the service sector. There is no excuse for the lack of detail in comparable industry sectors, particularly better data for NACE group 74.30.3 "Chemical testing and analysis" is needed. More detailed statistical data at this level would allow improved capacity estimations.

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Appendix

Appendix 1: Average prices for the tests as required by the REACH proposal: Overview by size of laboratory

Tests as specified in Appendix V-VIII of the REACH proposal	Test guide-lines: OECD / EU	No. of all labs	Avg. price: means in Euros			Large lab share of tot. capacity (%)
			All labs	Large labs	BAuA (2004) labs	
v 011 - Spectral data		10	2,094	2,626		40
v 012 - Analytical characterization		8	2,554	2,294		48
v 014 - Development of analytical method		9	5,239	9,500		85
v 5.02 - Melting point	102 / A.1	12	674	848	600	71
v 5.03 - Boiling point	103 / A.2	12	719	905	600	71
v 5.04 - Relative density	109 / A.3	11	657	829	600	72
v 5.05 - Vapour pressure	104 / A.4	8	2,779	3,211		84
v 5.06 - Surface tension	115	12	817	976	800	70
v 5.07 - Water solubility	105	11	3,813	4,508	3,900	78
v 5.08 - Partition coefficient	117 & 107	10	3,248	4,034	3,000	76
v 5.09 - Flash-point	A.9	11	809	896	800	75
v 5.10 - Flammability	A.10	9	812	912		77
v 5.11 - Explosive properties	A.14	9	2,284	1,885	3,300	76
v 5.12 - Self-iginition temperature	A.15 or 16	9	1,338	1,646	1,800	82
v 5.13 - Oxidising properties	A.17	9	2,144	2,611	2,700	74
v 5.14 - Granulometry	ECB Guidel.	6	1,328	1,318		92
vii 5.18 - Stability in organic solvents	105	5	3,496	4,427		76
vii 5.19 - Dissociation constant	112	8	3,216	4,663		76
vii 5.20 - Viscosity	114	7	860	1,281		66
v 6.1 - In vitro skin irritation/corrosion	430 & 431	4	1,645	1,893		98
vi 6.1.1 - In vivo skin irritation/corrosion	404	10	1,194	1,494	1,200	83
v 6.2 - In vitro eye irritation/corrosion		4	1,615	1,615		100
vi 6.2.1 - In vivo eye irritation/corrosion	405	12	1,343	1,650	1,100	86
v 6.3 - Skin sensitisation (LLNA)	406	8	3,959	4,668	3,200	88
v 6.4.1 - In vitro gene mutation study (Ames test)		11	3,174	3,204	2,900	91
vi 6.4.2 - In vitro cytogenicity study in mammalian cells (CA)	473	11	19,161	19,217	15,000	86

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vi 6.4.2 - In vitro cytogenicity study in mammalian cells (MNT)	473	2	11,000	6,000		100
vi 6.4.3 - In vitro gene mut. study in mammal. cells (MLA)	476	7	16,603	15,644		98
vi 6.4.3 - In vitro gene mut. study in mammal. cells (HPRT)	476	6	17,283	17,933	13,000	86
vii 6.4 - Mouse micronucleus assay	474	9	11,268	11,785	11,000	90
viii 6.4.4 - Further in vivo mutagen.study: micronucleus or UDS test		4	18,898	21,864	22,000	100
vi 6.5.1 - Acute toxicity, oral route (rats)	423	10	1,474	1,639	1,400	79
vi 6.5.2 - Acute toxicity, inhalation route (rats)	403 / B.2	5	11,734	11,151	9,600	97
vi 6.5.3 - Acute toxicity, dermal route (rats)	402	10	2,011	2,470	2,000	88
vi 6.6.1a - Short-term repeated dose toxicity: 28 days, oral (rats)	407	10	49,390	55,360	40,600	89
vi 6.6.1b - Short-term repeated dose tox.: 28 days, inhalation (rats)	412	5	105,455	99,092	71,700	95
vii 6.6.1c - Further short-term repeated dose tox.: 28 days, dermal (rabbit)	410	6	49,550	48,175		93
vii 6.6.1d - Further short-term repeated dose tox.: 28 days, inhalation		1	99,000	99,000		100
vii 6.6.2 - Sub-chronic repeated dose tox. study: 90 days, oral (rats)	408	8	115,656	119,450	110,000	92
viii 6.6.3 - Long-term repeated dose tox. study (longer than 12 month)		6	372,000	382,500	394,000	90
vi 6.7.1 - Screening for reproduction/developmental tox.(rats)	421	8	54,597	54,129		96
vi 6.7.2 - Developmental toxicity study (rats), oral gavage	e.g. 414	7	63,100	76,550	68,000	93
vi 6.7.2 - Developmental toxicity study (rabbits), oral gavage	e.g. 414	2	92,500	.		67
vii 6.7.3 - Two-generation reproduction tox. study, oral gavage	416	8	327,975	313,967	250,000	93
vi 6.8.1 - Assessment of toxicokinetic behaviour		6	33,041	49,161	76,000	90
viii 6.8.2 - Further studies on toxicity of particular concern		2	101,250	101,250		100
viii 6.9 - Carcinogenicity study (rats)	451	7	780,357	787,083	767,000	97
v 7.1.1 - Short-term acute toxicity study on daphnia	202 / C.2	13	3,742	4,900	5,400	69
v 7.1.2 - Growth inhibition study on algae	201 / C.3	14	4,510	5,841	5,700	72
v 7.1.3 - Short-term acute toxicity study on fish	203 / C.1	12	4,193	6,203	6,100	75
v 7.1.4 - Activated sludge respiration inhibition testing	209 / L133	12	2,215	3,087	2,300	73
vii 7.1.5 - Long-term toxicity study on daphnia, 21 days	211	13	13,426	18,092	11,000	74
vii 7.1.6 - Long-term toxicity study on fish	e.g. 204	8	9,319	12,018		77
vii 7.1.6.1- Fish early-life stage (FELS) toxicity test	210	11	26,254	30,823	39,000	54
vii 7.1.6.2- Fish short-term tox. test on	212	7	10,238	27,413		21

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embryo & sac-fry stages						
vii 7.1.6.3- Fish, juvenile growth test	215	8	16,462	21,466		91
vi 7.2.1.1 - Ready biodegradability	301	14	3,901	4,803	4,800	64
vii 7.2.1.2 - Simul. test. on ultimate degrad. in surface water	302	6	6,342	5,813	4,000	39
vii 7.2.1.3 - Soil simulation testing (for subst. adsorbing to soil)		6	35,792	43,583		76
vii 7.2.1.4 - Sediment simulat. test. (for subst. adsorb. to sedim.)		5	46,250	41,083		75
viii 7.2.1.5- Further studies on confirmatory biodegration rates	303A	4	17,325	40,000	20,000	72
vi 7.2.2.1 - Abiotic degradation: Hydrolysis as a function of pH	C.7	13	6,573	7,032	9,200	92
vii 7.2.3 - Identification of degradation products		1	2,000	.		100
vi 7.3.1 - Adsorption/desorption sceening study (HPLC method)	121	12	3,878	5,187	2,200	89
vii 7.3.2 - Bioconcentration in (one) aquatic species, preferably fish	305	6	40,333	112,500	122,000	74
vii 7.3.3 - Further studies on adsorption/desorption		7	19,634	26,060	20,200	78
viii 7.3.4 - Further environmental fate and behaviour studies		1	97,500	97,500		100
vii 7.4.1 - Short-term toxicity testing on earthworms	207 / L133	11	4,160	4,491	4,000	61
vii 7.4.2 - Effects on soil micro-organisms	ISO 11267	6	11,765	18,263		74
vii 7.4.3 - Short-term toxicity testing on plants	208	5	7,565	10,988	8,000	36
viii 7.4.4 - Long-term toxicity testing on earthworms	ISO 11268-2	6	8,580	6,289		56
viii 7.4.5 - Long-term toxicity testing on soil invertebrates		2	8,574	10,148		17
viii 7.4.6 - Long-term toxicity testing on plants		0	.	.		100
viii 7.5 - Long-term toxicity testing on sediment organisms		5	14,966	17,776		73
viii 7.6 - Long-term or reproductive toxicity to birds:	206	3	96,167	79,500		100
vii 9. - Descript. of the analyt. methods of detect. and analysis		1	750	750		100
- Vapour pressure, calculation					1,400	
- Vapour pressure, static, others					3,000	
- Vapour pressure, gas saturation					4,900	
- Flammability (solids)					600	
- Flammability (contact with water)					1,100	
- Subchronic inhalative, EU B.29					198,000	
- Fertility one generation, EU B.34					124,000	
- Metabolism study, OECD 417					150,000	

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Appendix 2: Average and maximum testing capacity of small and large laboratories (in units of test per annum)

Tests as specified in Appendix V-VIII of the REACH proposal	Test guide-lines: OECD / EU	Avg. capacity					Max. capacity	
		Small labs	Large labs	All labs		Large lab share of tot. capacity (%)	All labs	
		Total	Total	N	Total		N	Total
v 011 - Spectral data		429	285	7	714	40	9	1,197
v 012 - Analytical characterization		269	250	8	519	48	8	855
v 014 - Development of analytical method		47	272	8	319	85	10	644
v 5.02 - Melting point	102 / A.1	190	462	12	652	71	13	1,168
v 5.03 - Boiling point	103 / A.2	190	462	12	652	71	13	1,168
v 5.04 - Relative density	109 / A.3	180	457	11	637	72	13	1,393
v 5.05 - Vapour pressure	104 / A.4	65	331	9	396	84	10	730
v 5.06 - Surface tension	115	196	452	12	648	70	14	1,423
v 5.07 - Water solubility	105	100	372	14	474	78	15	849
v 5.08 - Partition coefficient	117 & 107	113	372	14	487	76	15	857
v 5.09 - Flash-point	A.9	135	403	12	538	75	14	1,333
v 5.10 - Flammability	A.10	128	417	12	545	77	13	1,158
v 5.11 - Explosive properties	A.14	72	230	11	302	76	12	680
v 5.12 - Self-iginition temperature	A.15 or 16	92	428	11	520	82	12	1,125
v 5.13 - Oxidising properties	A.17	81	234	11	315	74	12	1,003
v 5.14 - Granulometry	ECB Guidel.	31	360	7	391	92	6	470
vii 5.18 - Stability in organic solvents	105	21	66	6	87	76	7	515
vii 5.19 - Dissociation constant	112	61	192	9	253	76	10	695
vii 5.20 - Viscosity	114	135	265	8	400	66	10	968
v 6.1 - In vitro skin irritation/corrosion	430 & 431	10	464	8	474	98	9	1,278
vi 6.1.1 - In vivo skin irritation/corrosion	404	145	698	12	843	83	13	2,028
v 6.2 - In vitro eye irritation/corrosion		.	425	7	425	100	9	1,138
vi 6.2.1 - In vivo eye irritation/corrosion	405	140	843	13	983	86	14	2,173
v 6.3 - Skin sensitisation (LLNA)	406	110	839	12	949	88	13	1,969
v 6.4.1 - In vitro gene mutation study (Ames test)		110	1,176	13	1,286	91	14	2,638
vi 6.4.2 - In vitro cytogenicity study in mammalian cells (CA)	473	35	224	12	259	86	13	464
vi 6.4.2 - In vitro cytogenicity study in mammalian cells (MNT)	473	.	28	3	28	100	3	40
vi 6.4.3 - In vitro gene mut. study in mammal. cells (MLA)	476	4	171	9	175	98	9	374
vi 6.4.3 - In vitro gene mut. study in mammal. cells (HPRT)	476	7	44	6	51	86	6	59

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vii 6.4 - Mouse micronucleus assay	474	19	165	11	184	90	12	337
viii 6.4.4 - Further in vivo mutagen.study: micronucleus or UDS test		.	76	6	76	100	6	116
vi 6.5.1 - Acute toxicity, oral route (rats)	423	250	942	13	1,192	79	14	2,692
vi 6.5.2 - Acute toxicity, inhalation route (rats)	403 / B.2	6	180	9	186	97	10	394
vi 6.5.3 - Acute toxicity, dermal route (rats)	402	70	505	13	575	88	14	1,670
vi 6.6.1a - Short-term repeated dose toxicity: 28 days, oral (rats)	407	31	262	13	293	89	14	460
vi 6.6.1b - Short-term repeated dose tox.: 28 days, inhalation (rats)	412	1	20	8	21	95	9	64
vii 6.6.1c - Further short-term repeated dose tox.: 28 days, dermal (rabbit)	410	2	26	10	28	93	11	161
vii 6.6.1d - Further short-term repeated dose tox.: 28 days, inhalation		.	6	2	6	100	2	10
vii 6.6.2 - Sub-chronic repeated dose tox. study: 90 days, oral (rats)	408	13	154	12	167	92	13	251
viii 6.6.3 - Long-term repeated dose tox. study (longer than 12 month)		2	19	10	21	90	11	66
vi 6.7.1 - Screening for reproduction/developmental tox.(rats)	421	3	65	11	68	96	12	132
vi 6.7.2 - Developmental toxicity study (rats), oral gavage	e.g. 414	6	86	12	92	93	13	165
vi 6.7.2 - Developmental toxicity study (rabbits), oral gavage	e.g. 414	4	8	3	12	67	3	22
vii 6.7.3 - Two-generation reproduction tox. study, oral gavage	416	2	26	11	28	93	12	59
vi 6.8.1 - Assessment of toxicokinetic behaviour		20	177	6	197	90	6	388
viii 6.8.2 - Further studies on toxicity of particular concern		.	26	5	26	100	6	147
viii 6.9 - Carcinogenicity study (rats)	451	1	28	11	29	97	12	57
v 7.1.1 - Short-term acute toxicity study on daphnia	202 / C.2	143	368	14	536	69	16	1,290
v 7.1.2 - Growth inhibition study on algae	201 / C.3	122	360	15	497	72	16	1,091
v 7.1.3 - Short-term acute toxicity study on fish	203 / C.1	108	387	15	515	75	17	1,096
v 7.1.4 - Activated sludge respiration inhibition testing	209 / L133	83	233	14	318	73	15	774
vii 7.1.5 - Long-term toxicity study on daphnia, 21 days	211	23	80	13	108	74	14	236
vii 7.1.6 - Long-term toxicity study on fish	e.g. 204	17	57	11	74	77	12	194
vii 7.1.6.1- Fish early-life stage (FELS) toxicity test	210	14	20	12	37	54	13	126
vii 7.1.6.2- Fish short-term tox. test on embryo & sac-fry stages	212	25	7	10	33	21	11	137
vii 7.1.6.3- Fish, juvenile growth test	215	3	30	9	33	91	10	100
vi 7.2.1.1 - Ready biodegradability	301	167	317	14	496	64	17	1,169
vii 7.2.1.2 - Simul. test. on ultimate degrad. in surface water	302	25	16	6	41	39	7	172
vii 7.2.1.3 - Soil simulation testing (for subst. adsorbing to soil)		2	22	7	29	76	7	61

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vii 7.2.1.4 - Sediment simulat. test. (for subst. adsorb. to sedim.)		1	9	6	12	75	6	30
viii 7.2.1.5- Further studies on confirmatory biodegration rates	303A	13	34	6	47	72	7	193
vi 7.2.2.1 - Abiotic degradation: Hydrolysis as a function of pH	C.7	30	361	15	393	92	16	681
vii 7.2.3 - Identification of degradation products		.	55	3	55	100	4	108
vi 7.3.1 - Adsorption/desorption sceening study (HPLC method)	121	40	318	13	358	89	14	560
vii 7.3.2 - Bioconcentration in (one) aquatic species, preferably fish	305	4	14	8	19	74	10	62
vii 7.3.3 - Further studies on adsorption/desorption		20	81	8	104	78	8	172
viii 7.3.4 - Further environmental fate and behaviour studies		.	20	2	20	100	2	35
vii 7.4.1 - Short-term toxicity testing on earthworms	207 / L133	26	41	10	67	61	12	283
vii 7.4.2 - Effects on soil micro-organisms	ISO 11267	3	14	7	19	74	8	91
vii 7.4.3 - Short-term toxicity testing on plants	208	16	9	6	25	36	8	77
viii 7.4.4 - Long-term toxicity testing on earthworms	ISO 11268-2	7	9	7	16	56	10	111
viii 7.4.5 - Long-term toxicity testing on soil invertebrates		.	1	2	6	17	3	75
viii 7.4.6 - Long-term toxicity testing on plants		.	12	2	12	100	2	25
viii 7.5 - Long-term toxicity testing on sediment organisms		3	22	6	30	73	7	80
viii 7.6 - Long-term or reproductive toxicity to birds:	206	.	9	3	9	100	5	116
vii 9. - Descript. of the analyt. methods of detect. and analysis		.	1	1	1	100	2	60

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