2. Quantifying the costs and savings of the OECD Environment, Health and Safety Programme

This chapter summarises the approach used to quantify the costs to governments and industry participating in the OECD Environment, Health and Safety Programme as well as the savings they derive from participating in the programme. It looks at the costs to the participating countries' and Secretariat costs. It then discusses the savings due to reducing duplicative testing of new and existing industrial chemicals, pesticides and biocides; using harmonised dossiers for pesticide registrations and harmonised country pesticide review reports; and reducing the number of test animals.

2.1. Background

In 2010, a report published by the OECD Environment, Health and Safety (EHS) Programme documented cost savings to governments and the chemicals and pesticide industries in OECD countries, from participating in the work of, and benefiting from the products developed by, the EHS Programme (OECD, 2010). The report, based on data from 2006-08, estimated that net savings (after deducting participation and OECD Secretariat costs) were around EUR 177 million a year,[1] not counting non-quantifiable savings and other benefits.

As the programme has evolved, new opportunities for work sharing are bringing even more benefits to society, particularly with regard to progress made on (Quantitative) Structure-Activity Relationships - or (Q)SARs - and read-across (see Box 2.2), the OECD (Q)SAR Toolbox, and other risk assessment guidance documents and formats. Ten years on since the last collection of data, it is time to reassess the programme and the benefits it offers in the light of these changes as well as to quantify additional benefits to governments and industry from EHS work on biocides, which were not evaluated in the previous report. This chapter summarises the approach used to quantify the costs to governments and industry of participating in the EHS Programme and the savings they derive from participating in the programme. Chapter 3 summarises the many and substantial non-quantifiable benefits for governments and industry of participating in the EHS Programme.

Four surveys[2] were conducted in April 2018 to collect data from OECD governments (see Table A.1 in Annex A) and the biocide, industrial chemicals and pesticide industries (see Table A.2 in Annex A). Additional data were collected from the OECD's Event Management System, which contains data on the number of OECD meetings held each day and the number of delegates registered for those meetings. Data from relevant reports in the literature have also been used to complement and confirm data collected via the surveys.

In this chapter, the costs of the EHS Programme are calculated first, followed by an assessment of the savings.[3] Costs are then subtracted from savings to reveal the net savings. The programme's costs and savings as presented in the report from 2010 (based on data from 2006-08) are compared with those in 2019 (based on data from 2016-18) at the end of each section.

2.2. Quantifying the costs of the EHS Programme

There are two main types of costs involved in implementing the EHS Programme:

1. Secretariat costs: OECD Secretariat support, including staff salaries, benefits and travel; consultants and invited experts; and general overhead.
2. Country costs: the costs to delegates of participating in and contributing to the work of the EHS Programme. These include both travel costs to attend OECD meetings and staff costs for developing and reviewing EHS documents and preparing for and attending EHS meetings.

The following baselines and calculations were used for this analysis:

- Secretariat costs were based on the OECD Programme of Work and Budget for the years 2016 and 2017.
- Country staff costs were calculated based on the number of delegates who participated in EHS meetings, the average length of those meetings, the time

delegates spent preparing for the meetings and their average hourly wage. The figures used for the number of meetings, length of meetings and number of participants to those meetings were based on data collected from OECD's Event Management System and were averaged to compensate for yearly fluctuations in meeting frequencies. The average hourly wage across countries, as well as the average preparation time for the meetings (as a percentage of meeting time), were based on the results of the EHS survey of governments (see Annex A).

- Country travel costs were based on a weighted average of the costs of flights from five regions from which delegates travelled to OECD meetings during 2016 and 2017 (North America, South America, Europe, Asia/Pacific, and South and Southeast Asia). These costs also include the average daily expenses for delegates' meals and accommodation (i.e. EUR 304, based on discussions with government delegates).

2.2.1. Overall costs

Table 2.1 shows the estimated annual costs of the EHS Programme (averaged over two years). Box 2.1 compares the Secretariat costs in 2010 and 2019[4].

Table 2.1. **Estimated total annual costs of supporting the EHS Programme**

Country costs	
Number of meetings	42
Average length of meetings (days)	2.11
Average number of participants	1 239.50
Travel costs[1]	EUR 1 455 000
Country staff costs[2]	EUR 2 354 000
Total country costs	EUR 3 809 000
Secretariat costs	
Expenditure on permanent staff and consultancy funds	EUR 1 866 000
Extrabudgetary Chemicals Management Programme	EUR 2 679 000
Total Secretariat costs	EUR 4 545 000
Total costs (Secretariat + countries)	**EUR 8 354 000**

Notes:
1. Travel costs (rounded) = travel [weighted average cost of round-trip flight (EUR 532.64) x number of participants (1 239.50)] + expenses [length of meetings (2.11 days) x daily expenses (EUR 304) x number of participants (1 239.50)].
2. Country staff costs (rounded) = participation [length of meetings in hours (2.11 x 8 = 16.88) x number of participants (1 239.50) x staff costs per hour (EUR 45)] + preparation [(150% x 16.88 = 28.86) x number of participants (1 239.50) x staff costs per hour (EUR 45)].

Box 2.1. **Comparison of Secretariat and country costs, 2010 and 2019**

Total Secretariat costs have grown by 10% in real terms over the period 2010 to 2019, from EUR 4 137 814 in 2010 to EUR 4 545 000 in 2019. At the same time, there has been a substantial decline in country costs (68%) – due to a decrease in the number of meetings held each year – such that the overall cost of the EHS programme has been reduced by EUR 9 247 720 per year (50%), from EUR 17 601 720 in 2010 to EUR 8 354 000 in 2019. The reduction in the number of meetings is a result of the much wider use of conference calls rather than in-person meetings.

2.3. Quantifying the savings from the EHS Programme

There are both quantifiable and non-quantifiable benefits from the EHS Programme that accrue to government and industry. The savings associated with testing and assessing new pesticides and biocides, as well as new and existing industrial chemicals, can be relatively easily quantified in monetary terms. These are presented in Table 2.2. (Table 2.2 also quantifies the number of animals that are not needed each year for only testing new industrial chemicals, due to the work of the EHS Programme. That is, it does not include reductions in animals needed each year for testing existing industrial chemicals, biocides and pesticides.)

Other activities within the EHS Programme can currently only be described in qualitative terms, either because the benefits are not easy to measure in direct monetary gains, or else because the activities have not been implemented for a sufficient length of time to gauge their impact. However, the programme's qualitative benefits are no less real, less likely to occur or less important than the quantifiable benefits. They are listed in Chapter 3.

Table 2.2. **Annual benefits of the EHS Programme**

Savings	
From no repeat pesticide testing	EUR 206 937 500
From no repeat new industrial chemical testing	EUR 44 728 943
From no repeat biocide testing	EUR 61 250 000
From no repeat existing chemical testing	EUR 780 570
From harmonised pesticide monographs	EUR 2 218 145
From harmonised pesticide dossiers	EUR 1 951 125
Savings subtotal (rounded)	EUR 317 870 000
Costs	
Country	EUR 3 809 000
OECD Secretariat	EUR 4 545 000
Costs subtotal (rounded)	EUR 8 354 000
Net savings (rounded)	**EUR 309 516 000**
Reduction in animals needed for testing new industrial chemicals	32 702

2.3.1. Assumptions

One of the principal values of the EHS Programme is that it helps to reduce duplication of work for industry and governments. As described above, the potential for duplication is great, given the international character of biocides, industrial chemicals, and pesticide products developed for and sold in multiple markets. To calculate the extent to which OECD work helps to avoid such duplication, several assumptions were made:

- Each (often multinational) company that in a given year conducted safety testing and notified or registered a new biocide, industrial chemical or pesticide in one or more countries in one OECD region (see the paragraph below) also did this in the other regions made up of OECD member countries and the six non-members who are full adherents to OECD's MAD system (i.e. Argentina, Brazil, India, Malaysia, Singapore and South Africa).
- In this report, OECD member countries and the non-member full adherent countries to MAD are generally not considered individually, but rather as part of major regional markets. In the 2010 report, based on responses to questionnaires completed by the chemicals and pesticides industries, companies reported that, in

general, they marketed their products to three OECD regions (Asia/Pacific, Europe and North America) and that because of the OECD MAD system, data generated in one region would be accepted in the two other regions. However, this does not account for savings that accrue to non-members (and their industries) that are full adherents to MAD (Argentina, Brazil, India, Malaysia, Singapore and South Africa). Further, the OECD's membership has grown from 30 member countries in 2010 to 37 today with the addition of Chile, Colombia,[5] Estonia, Israel, Latvia, Lithuania and Slovenia. Depending on the industrial sector, a conservative estimate based on the results from the latest survey (Annex B) reveals that the average number of OECD regions to which products are marketed now ranges from 3 to 3.5. (A breakdown of the countries and regions considered in this report can be found in Annex C.) Again, it was assumed that for each new product notified or registered in one region, this was also done in the other regions.

- Without the OECD MAD system, slightly different test methods and GLP principles would have been developed by each country/region independently. Based on the results of the EHS surveys of the biocides, pesticides and industrial chemical industries (see Table A.2 in Annex A), it is estimated that in the absence of the EHS Programme, Country B would not accept the following shares of biocides, pesticides and industrial chemical industries' test data emerging from Country A because of differing methods, and therefore, that testing would have to be repeated:
  - 30% of the test data for industrial chemicals
  - 35% of test data for new pesticides
  - 35% of the test data for *biocides*

  It follows from the above that approximately 65% to 70% of the data *would* be accepted in Country B, even if the data does not fully conform to the requirements of that country[6]. This shows that these are quite conservative estimates, as countries are unlikely to accept such a high share of test data that is based on a different methodology than their own.
- In the *absence* of the OECD principles and guidance, it would be less likely that a (Q)SAR/category/read-across result (Box 2.2) used in one country/region for industrial chemicals would be accepted in another country/region. The same rate of acceptance of (Q)SAR data and results from categories/read-across was assumed as for testing (i.e. 30% of (Q)SAR results developed in one country would not be accepted in another). This rate is roughly in line with the rate estimated in the 2010 report (36%).

Box 2.2. **(Quantitative) structure-activity relationships and the (Q)SAR Toolbox**

(Quantitative) structure-activity relationships, or (Q)SARs, are mathematical approaches designed to find relationships between the chemical structures (or structure-related properties) and biological activity (or target property) of the studied compounds. Convergence of use of data from these models was facilitated by the publication of the *OECD Principles for the Validation, for Regulatory Purposes, of (Q)SAR Methods* (OECD, 2004) and the OECD *Guidance on Grouping of Chemicals* (OECD, 2007, updated in 2014). Prior to the adoption of the OECD guidance, the use of (Q)SAR results or data from categories/read-across (i.e. techniques for filling data gaps within chemical categories)[1] was, in general, limited to the country which generated these results (OECD, 2006).

Since the 2010 report, the OECD has undertaken further work on (Q)SARs. The OECD (Q)SAR project works to facilitate the practical application of (Q)SAR approaches in regulatory contexts and improve their regulatory use through the development of principles for the validation of (Q)SAR models, guidance documents and the development of the OECD (Q)SAR Toolbox. Version 1 of the Toolbox was released in March 2008 and the most recent version (4.2) was released in January 2018. It has benefited from the contributions of numerous experts in governments, non-governmental organisations and the chemical industry and is designed to help registrants and authorities to, among other things, fill data gaps by read-across, trend analysis and (Q)SARs.

By providing non-testing information on toxicological and ecotoxicological endpoints, where it can be applied, the Toolbox reduces the need for laboratory experiments. In this way, both the cost of the information requirements and the number of animals used in testing is reduced for those substances.

1. The principle of the read-across technique is that endpoint or test information for one chemical is used to predict the same endpoint or test information for another chemical, which is considered to be similar by scientific justification. A chemical used to make an estimate can be referred to as a source chemical, and a chemical for which an endpoint is estimated can be referred to as a target chemical.

2.4. Reducing testing and repeat testing for new industrial chemicals

Each year, industrial chemical manufacturers notify governments of their intention to manufacture and market new substances. This notification is accompanied by a set of data to allow the safety of the chemical to be assessed. This may involve tests that range from the inexpensive (e.g. a skin irritation/corrosion study costs around EUR 2 192 – see Table B.1 in Annex B), to complicated and costly (e.g. a repeated dose toxicity study (all routes) costs around EUR 316 131). The level of information required for a new chemical assessment depends on the type of product being considered and its production volume. Analysis of data from the European Chemicals Agency (ECHA) on the actual number of new experimental studies undertaken on new substances between 2010 and 2016 (see Table B.2 in Annex B) suggests average statistical test costs of EUR 169 531 per substance.[7]

The same data set provides data on the number of new substances fulfilling data requirements using (Q)SARs/read-across. Analysis of these data suggests that the average cost saving through (Q)SARS/read-across, to a large extent supported by the OECD (Q)SAR Toolbox and guidance, is EUR 20 545 per substance. (*Note:* this ratio of statistical testing costs to (Q)SARs [90:10] is fairly close to the estimates provided from the industry

survey [95:5]). This means that in the absence of the OECD (Q)SAR Toolbox and guidance, it is estimated that new substance registration would cost EUR 190 076 per substance.

Having to repeat tests for each new market can be a significant obstacle to trade in chemicals. This analysis assumes that by using OECD Test Guidelines and GLP Principles, the OECD (Q)SAR Toolbox and associated guidance, and as a result of the MAD system, a company can be assured that its test data will be accepted for assessment by governments throughout the OECD and beyond. (According to the EHS survey of the industrial chemicals sector, on average, each new chemical is introduced in three regions.) As can be seen from Table 2.3, these efforts combined continue to generate significant savings for companies whose products are introduced in multiple markets.

Table 2.3. **Benefits of the Mutual Acceptance of Data system and the (Q)SAR Toolbox: Lowering the costs of launching new industrial chemicals**

Average number of substances introduced in three major OECD regions in 2018	332.3[1]
Average cost of testing per chemical	EUR 169 531[2]
Average savings (cost avoided) through (Q)SARs/read-across per chemical	EUR 20 545[2]
Total cost of testing in the absence of (Q)SARs	EUR 190 076[2]
Average number of regions into which the new chemical is marketed	3
Total cost of testing across all regions in the absence of Mutual Acceptance of Data (MAD) and OECD (Q)SAR Toolbox and guidance[3]	EUR 101 069 745
Total cost of testing across all regions with MAD and OECD (Q)SAR Toolbox and associated guidance[4]	EUR 56 340 802
Annual savings due to the OECD Environment, Health and Safety Programme (MAD and (Q)SARs)	EUR 44 728 943
– of which through MAD[5]	EUR 39 894 265
– of which through application of (Q)SARs[6]	EUR 4 834 677

Notes:
1. Based on data from the EHS survey of governments (see Table A.1 in Annex A).
2. See Table B.2 in Annex B.
3. [Number of substances (332.3) x cost of testing without (Q)SARs (EUR 190 076)] + 2 x [percentage of tests not accepted (30%) x number of substances (332.3) x cost of testing without (Q)SARs (EUR 190 076)].
4. Number of substances (332.3) x cost of testing (169 531). This assumes there are little or no costs to generating (Q)SAR data.
5. [Testing costs (EUR 169 531) / total cost of testing in the absence of (Q)SARs (EUR 190 076)] x annual savings (EUR 44 728 943) = EUR 39 894 265.
6. [Average savings through (Q)SARs/read-across per chemical (EUR 20 545) / total cost of testing in the absence of (Q)SARs (EUR 190 076)] x annual savings (EUR 44 728 943).

In addition to the cost savings to industry through reductions in testing and repeat testing owing to MAD and the application of (Q)SARs/read-across, there is a substantial reduction in the number of test animals used to complete information requirements. The same methods used to estimate costs and cost savings above as a result of MAD and (Q)SARs/read-across can be applied to estimate the number of animals used for testing. Based on this approach, this report suggests a substantial reduction (56%) in the number of test animals that are needed (Table 2.4 and Box 2.3).

Table 2.4. **Benefits of the Mutual Acceptance of Data system and the OECD (Q)SAR Toolbox: Reducing the number of test animals**

Average number of substances introduced in three OECD regions in 2018	332.3[1]
Average number of animals used in testing per chemical	76[2]
Average number of test animals avoided through use of (Q)SARs/read-across per chemical	33[2]
Total number of test animals that would be used in the absence of (Q)SARs per chemical	109[2]
Total number of test animals that would be used across all three regions in absence of Mutual Acceptance of Data (MAD) and the OECD (Q)SAR Toolbox and associated guidance[3]	57 959
Total number of test animals used across all three regions with MAD and (Q)SARs[4]	25 257
Annual reductions in test animals due to the OECD Environment, Health and Safety Programme (MAD and (Q)SARs)	32 702
– of which through MAD[5]	22 801
– of which through application of (Q)SARs[6]	9 901

Notes:
1. Based on data from the EHS survey of governments (see Table A.1 in Annex A).
2. See Table B.2 in Annex B.
3. [Number of substances (332.3) x test animals without (Q)SARs (109)] + 2 x [percentage of tests not accepted (30%) x number of substances (332.3) x test animals without (Q)SARs (109)].
4. Number of substances (332.3) x test animals for experimental studies (76).
5. [Average number of animals used in testing (76) / total number of animals used in absence of (Q)SARs (109)] x annual reductions in test animals due to MAD and (Q)SARs (32 702).
6. [Average number of animals avoided through (Q)SARs/read-across per chemical (33) / total number of animals used in absence of (Q)SARs (109)] x annual reductions in test animals due to MAD and (Q)SARs (32 702).

Box 2.3. **Report on significant reduction in animal testing due to the use of read-across and (Q)SARs**

Stanton and Kruszewski (2016) found that through the use of read-across and (Q)SAR techniques to fill data gaps for 261 chemical substances, 100 000 to 150 000 test animals were not needed, and USD 50 million to USD 70 million in testing costs were avoided.

2.5. Reducing repeat testing for new pesticides

According to the survey responses received from pesticide manufacturers, the average testing cost to generate the extensive data package required for a new pesticide is around EUR 21.5 million.

Having to repeat tests for each new market can be a significant obstacle to trade in pesticides. This OECD analysis assumes that by using OECD Test Guidelines and GLP Principles, and as a result of the MAD system, a company can be assured that its test data will be accepted for assessment by governments throughout the OECD and beyond, i.e. in 3.5 regions.[8] As can be seen from Table 2.5, the MAD system has therefore generated, and continues to generate, significant savings for companies whose products are introduced in multiple markets.

Table 2.5. **Mutual Acceptance of Data system benefits: Lowering the costs of launching new pesticides**

Average number of substances introduced in each of the 3.5 major OECD regions in 2018	11[1]
Average cost of testing per chemical	EUR 21 500 000[2]
Total cost of testing across all 3.5 regions in the absence of Mutual Acceptance of Data (MAD)[3]	EUR 443 437 500
Total cost of testing across all 3.5 regions with MAD[4]	EUR 236 500 000
Annual savings due to the OECD Environment, Health and Safety Programme	EUR 206 937 500

Notes:
1. Based on data from the EHS survey of governments (see Table A.1 in Annex A).
2. Based on data from the EHS survey of industry (see Table A.2 in Annex A).
3. [Number of new pesticides per year (11) x cost of testing (EUR 21.5 million)] + 2.5 [percentage of tests that would have to be repeated without MAD (35%) x number of new pesticides (11) x cost of testing (EUR 21.5 million)].
4. Number of new pesticides per year (11) x cost of testing (EUR 21.5 million).

Box 2.4. **Comparison of testing costs, 2010 and 2019**

Net savings for pesticide manufacturers due to the use of OECD Test Guidelines/Good Laboratory Practice Principles rose from EUR 155 627 500 in 2010 to EUR 206 937 500 in 2019 (+33%). This increase is probably due to the following reasons:

- This report considers 0.5 additional regional markets.
- An increase in the cost of testing pesticide active ingredients for toxicity and environmental chemistry (investigation of the physical and metabolic breakdown of a potential product and assessment of the residues in plant, animal, soil and water systems), attributable to a rise in regulatory bodies' health and environmental safety data requirements. As a consequence, around 45 new Test Guidelines and 51 updated/corrected Test Guidelines have been published since 2008.

2.6. Harmonising industry dossiers for pesticides registration

The OECD Pesticides Programme aims to improve the efficiency of pesticide registration and re-registration and reduce the costs to industry and governments of the pesticide approval process. Given the extensive experience of governments and industry with pesticide registration and re-registration, costs could be reduced through greater co-operation among countries in sharing data and assessments.

One approach to reducing the time and effort needed for pesticide (re-)registration is to harmonise national formats for the registration dossiers used by industry to submit data. A harmonised format means that once a company compiles a dossier for one country, the cost and time involved in developing dossiers for other countries will be significantly reduced. The OECD has a standard dossier format (OECD, 2005a) which pesticide companies can use when submitting data to member countries. According to the EHS survey of the pesticides industry, the total cost of preparing a dossier on a pesticide is EUR 236 500 (not including the cost of testing). Industry has estimated that using the OECD format saves an average of 70% of the costs of developing a dossier on the same substance for a second country. In other words, using the OECD dossier format for a substance being introduced into a second country only costs a company 30% of the cost of the first dossier on the same

substance. On the other hand, if the first dossier was not developed using the OECD dossier format, it is estimated to cost a company 60% of the cost of the first dossier to develop a second dossier. Based on the responses to the EHS survey of governments (see Table A.1 in Annex A), on average, 11 new pesticides enter the market each year, and each is introduced into, on average, 3.5 regional markets (meaning a company will need to prepare an average of 3.5 dossiers for each substance). Based on these assumptions, the savings to the pesticides industry from using the OECD format would therefore be EUR 1.95 million per year (Table 2.6).

It should be noted that this methodology only accounts for the savings that accrue to industry for the submission of dossiers for new active ingredients, not for the submission of dossiers for pesticide products which contain those active ingredients or for existing active ingredients which undergo periodic re-reviews but which may still use portions of the OECD dossier format.

Table 2.6. **Annual savings to industry from harmonised dossiers for pesticide registrations**

Number of new pesticides to be registered	11
Cost to prepare one dossier	EUR 236 500
Total cost to prepare dossiers for all new pesticides across all 3.5 regions without OECD harmonised dossier[1]	EUR 6 503 750
Total cost to prepare dossiers for all new pesticides across all 3.5 regions with OECD harmonised dossier[2]	EUR 4 552 625
Yearly savings due to OECD Environment, Health and Safety Programme	EUR 1 951 125

Notes:
1. (11 x EUR 236 500) + (11 x EUR 141 900) (second dossier costs 60% of the original one) x 2.5 (regions).
2. (11 x EUR 236 500) + (11 x EUR 70 950) (second dossier costs 30% of the original one) x 2.5 (regions).

Box 2.5. **Comparison of pesticide industry savings from using the OECD dossier format, 2010 and 2019**

The estimated annual savings from using the OECD dossier format has increased by 9%, from EUR 1 787 885 in 2010 to EUR 1 951 125 in 2019. Much of the additional savings are due to the consideration of 0.5 additional regional markets.

2.7. Harmonising country review reports for pesticide registration

Just as harmonising the formats used in industry registration dossiers significantly reduces costs and time for industry, harmonising the formats of country reports (monographs) which review pesticide registration submissions can also provide substantial benefits by allowing the information to be shared across governments and by allowing joint reviews of the same pesticides (see OECD, 2005b). The OECD has developed a standard monograph format[9] which governments can use to prepare their country reports.

Based on information provided in the EHS survey of governments (see Annex A), it is estimated that reviewing a full industry dossier on a new pesticide and writing a comprehensive report (monograph) takes a government 1.95 person-years. However, by using another country's monograph for the same pesticide – based on the OECD monograph format – government experts estimate that 1.02 full person-years of time would be saved (i.e. 52%), thus generating significant savings (Table 2.7). The savings in

Table 2.7 are estimated based on average staff costs per hour in OECD countries (EUR 45)[10], and 240 working days per year.

Table 2.7. **Annual savings to governments from harmonised country pesticide review reports (monographs)**

Average number of new pesticide applications each year	11
Cost to review one dossier and prepare a monograph[1]	EUR 168 480
Total cost to review dossiers and prepare monographs on all new pesticides across all 3.5 regions without OECD harmonised report format[2]	EUR 6 486 480
Total cost to review dossiers and prepare monographs on all new pesticides across all 3.5 regions with OECD harmonised report format[3]	EUR 4 268 336
Annual savings due to OECD Environment, Health and Safety Programme	EUR 2 218 145

Notes:
1. 8 hours/day x EUR 45/hour x 240 working days/year x 1.95 person-years.
2. EUR 168 480 x 11 new pesticides x 3.5 regions.
3. [EUR 168 480 x 11] + 2.5 x [52.13% (EUR 168 480 x 11)].

Box 2.6. **Comparison of government cost savings from using the OECD monograph formats, 2010 and 2019**

The savings from harmonised country review reports for pesticides in 2019 (EUR 2 218 145) represented a close to 8% decline compared to the estimated savings in 2010 (EUR 2 408 700 adjusted for inflation). This drop may have been the result of the decrease in: the average number of pesticide applications per year, from 12 in 2010 to 11 in 2019; the time needed to develop a monograph, from 2.2 to 1.95 person-years, even with the increase in the number of regions from 3 to 3.5 and the hourly cost of government staff from EUR 36 to EUR 45.

2.8. Reducing repeat testing for new biocides

The present report considers the savings for industry attributable to OECD Test Guidelines and GLP Principles for new biocidal active substances too. (These savings were not calculated in the 2010 report.) According to the survey responses received and from the literature review (Cefic Sector Groups, 2017), the average testing cost to generate the data package required for new biocidal active substances is around EUR 5 million.

As with pesticides, having to repeat tests for each new market can be a significant obstacle to trade in biocides. As a result of the MAD system, a company can be assured that its test data will be accepted for assessment by governments throughout the OECD and beyond. The MAD system therefore generates significant savings for companies that introduce biocidal products into multiple markets (Table 2.8).

Table 2.8. **MAD system benefits: Lowering the costs of launching new biocidal active substances**

Average number of biocidal active substances introduced in each of the 3.5 major OECD regions per year	14[1]
Average cost of testing per biocidal active substance	EUR 5 000 000[2]
Total cost of testing across all 3.5 regions without Mutual Acceptance of Data (MAD)	EUR 131 250 000[3]
Total cost of testing across all 3.5 regions with MAD[4]	EUR 70 000 000[4]
2019 annual savings due to the OECD Environment, Health and Safety Programme	EUR 61 250 000

Notes:
1. Based on information provided by the governments of Canada, the EU and the United States.
2. Based on data from the EHS survey of industry (see Annex A) and literature review (Cefic Sector Groups, 2017).
3. [Number of new active substances per year (14) x cost of testing (EUR 5 million)] + 2.5 x [percentage of tests that would have to be repeated without MAD (35%) x number of new active substances (14) x cost of testing (EUR 5 million)].
4. Number of new active substances per year (14) x cost of testing (EUR 5 million).

It should be noted that this methodology only accounts for the savings that accrue to industry for the submission of test data for new active ingredients, not for the submission of test data for biocidal products which contain those active ingredients or for existing active ingredients which undergo periodic re-reviews.

2.9. Reducing testing and repeat testing for existing industrial chemicals

With regards to the benefits of the EHS Programme in terms of reducing the need for new testing and repeat testing of existing industrial chemicals, the 2010 report focused on the then active High Production Volume (HPV) Chemicals Programme (see Chapter 1). Under the HPV Chemicals Programme, industry and governments collected existing information or generated new information on HPV chemicals by testing or using non-test methods like (Q)SARs or read-across to create a basic set of data (Screening Information Data Set, or SIDS) on a chemical. Based on these data, governments prepared a SIDS Initial Assessment Report (SIAR) containing the key scientific data as well as a hazard assessment and recommendations for further work. As noted in Chapter 3, with the completion of work on HPV chemicals, the EHS has established the Cooperative Chemicals Assessment Programme and continues to develop guidance and other tools to promote and support the acceptance of alternative methods, such as (Q)SARs and read-across. These tools continue to result in benefits for industry associated with the generation of data used by governments in the assessment of existing industrial chemicals.

In particular, such benefits result from OECD work in the following ways:

- the cost to industry for testing is reduced as the OECD's harmonisation of the use of predictive models (i.e. (Q)SARs/read-across) and development of the OECD (Q)SAR Toolbox reduces the need for new experimental studies to support government assessments of existing chemicals
- the cost to industry for testing is further reduced, due to MAD, if the same existing substance is assessed in more than one country (i.e. no repeat testing).

The methodology to estimate the savings from the EHS Programme is similar to that used in the evaluation of the HPV Chemicals Programme for the 2010 report, and supported by responses to the industry survey as well as analyses conducted by Risk & Policy Analysts

Limited (RPA) (see Annex B). Please note that while only a few government figures were provided in response to the survey, these confirm the order of magnitude of the data below.

Three steps were taken to calculate the savings to industry of the OECD's work:

1. Step 1: Estimate the cost of testing for one chemical by a company in one country (Country A) taking into account data that can be generated using (Q)SARs/read-across. Note: this report assumes that the cost to generate data via (Q)SAR/read-across is minimal.
2. Step 2: Compare the cost for that same company which also markets the chemical in a second country (Country B) based on how much data the government in Country B would accept from Country A: 1) with the EHS Programme (i.e. MAD and OECD work on (Q)SARs/read-across); and 2) without the EHS Programme.
3. Step 3: Calculate the savings per chemical x the annual average number of existing chemical assessments governments indicated in their survey response that they use from another country, x the average number of regions in which existing chemicals are marketed.

Step 1: When a government assesses an existing chemical, it may use three sources of data: new test data; data generated by (Q)SARs/read-across; existing data. Table 2.9 provides estimates for the percentage of data generated by testing and (Q)SARs/read-across. The cost of testing is both for actual testing and the cost of testing avoided if a company generates data via (Q)SARs/read-across. The table provides estimates using two sources: the results of the survey of the industrial chemicals sector; data compiled by the RPA, and based on data from the ECHA's *Registration Database*. As discussed in Annex B, data from the ECHA *Registration Database* has been analysed by RPA to develop a statistical cost of new experimental studies and cost avoided for (Q)SARs/read-across for substances registered in the European Union. Across all existing substances, 46% of the required endpoints were satisfied by existing data, and 54% were satisfied by new data coming from either new tests or from (Q)SARs; specifically, 21% from new testing and 33% from (Q)SARs. Using costs associated with each of the specific test endpoints, the RPA has estimated that the cost of generating all of the new data to fill gaps using full testing only (simulating a situation where (Q)SARs do not exist) would have been EUR 137 100 per substance on average. Focusing solely on the generation of data (i.e. (Q)SARs and new testing make up 100% of such data), only 61% of the required new data for registration was generated by new tests and 39% was generated using (Q)SARs.[11]The cost of the new testing is estimated as EUR 83 631 per substance. Accordingly, the savings owing to the use of (Q)SARs is EUR 53 469 per substance.

Table 2.9. **Estimated costs of testing per chemical in a single country**

		Full testing for missing endpoints	Data actually provided by:	
			(Q)SAR/read-across	New testing
Industry responses to questionnaire	Percentage of total		12.5%[3]	87.5%[3]
	Cost	EUR 152 000[2]	EUR 19 000	EUR 133 000
Risk & Policy Analysts Limited (RPA)	Percentage of total		39%[4]	61%[4]
	Cost	EUR 137 100[1]	EUR 53 469	EUR 83 631

Notes:
1. Does not account for filling gaps with existing data; estimated based on data held by the European Chemicals Agency.

2. EUR 152 000 constitutes 80% of the EUR 190 000 testing costs reported in response to the EHS Survery of Industry (i.e. it excludes existing data which make up 20% of the total). The survey of industry indicated that of the data that are generated, 10% came from (Q)SARs and 70% from new data (see Annex A).
3. 12.5% and 87.5% equate to the original responses to the EHS survey of industry responses (i.e. 10% and 70%) when excluding existing data, i.e. 20% of the total (see Annex A).
4. The figures are taken from the RPA's analysis.

Step 2: Table 2.10 compares the cost for a second country (Country B) accepting data from Country A with the EHS Programme (i.e. MAD and OECD work on (Q)SARs) and without the EHS Programme. Note: based on the results of the survey of the industrial chemicals sector, it is estimated that without MAD, Country B would not accept 30% of the test data generated in Country A (i.e. 30% would have to be repeated). Further, in the absence of the OECD principles and guidance, it would be less likely that a (Q)SAR/read-across result used in Country A would be accepted in Country B. The same rate of acceptance of (Q)SAR/read-across data was assumed as for testing (i.e. 30% of (Q)SAR industrial chemical data developed in Country A would not be accepted in Country B). This rate is relatively similar to the rate estimated in the 2010 report (36%).

Table 2.10. **Cost comparison of testing per chemical with the Environment, Health and Safety Programme and without (i.e. withoug MAD and the OECD [Q]SAR Toolbox and associated guidance)**

	Country		With the EHS Programme	Without the EHS Programme	
				(% of country A's data not accepted) x (the testing costs for the remaining data)[1]	Testing costs
Industry responses	A	Cost of data generated via testing	EUR 133 000		EUR 133 000
		Cost of data generated with (Q)SARs/read-across/etc.[2]	0	0	0
	B	Cost of data generated via testing	0	30% (i.e. 30% of EUR 133 000)	EUR 39 900
		Cost of data generated with (Q)SARs/read-across/etc.[2]	0	30% (i.e. 30% of EUR 19 000)	EUR 5 700
	Total		EUR 133 000		EUR 178 600
	Savings				EUR 45 600
RPA's analysis[3]	A	Cost of data provided via testing	EUR 83 631		EUR 83 631
		Cost of data provided according to (Q)SARs/read-across/etc.[2]	0		EUR 0
	B	Cost of data provided via testing	0	30% (i.e. 30% of EUR 83 631)	EUR 25 089
		Cost of data provided according to (Q)SARs/read-across/etc.[2]	0	30% (i.e. 30% of EUR 53 469)	EUR 16 041
	Total		EUR 83 631		EUR 124 761
	Savings				EUR 41 130

Notes:
1. Data derived from Table 2.9.
2. It is assumed that the cost to provide data via (Q)SAR/read-across is minimal.
3. Estimates based on registration data from the European Chemicals Agency.

Step 3: Therefore, to determine the overall savings to industry, the savings per chemical are multiplied by the number of regions in which existing chemicals are marketed (from the EHS survey of industry), and the average yearly number of assessments one country uses from another (from the EHS survey of governments) – see Table 2.11.

Table 2.11. **Total annual savings associated with the testing of existing chemicals**

	Savings per chemical	Number of regions	Average yearly number of assessments one country uses from another	Total savings
Industry responses	EUR 45 600	3	6	EUR 820 800
Risk & Policy Analysts Limited (RPA)	EUR 41 130	3	6	EUR 740 340
Average industry and RPA				EUR 780 570

Box 2.7. **Other longer term benefits of the Mutual Acceptance of Data system and (Q)SARs for countries that have adopted REACH-like legislation**

The savings described above concern the annual benefits to industry from reduced testing of existing substances. But other one-off benefits can also be envisioned. Since the adoption of the EU REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) legislation, the European Union has registered approximately 21 500 chemicals (ECHA, n.d.). Thus, registration dossiers – containing the types of test data and (Q)SAR results described above – have been prepared.

Since the EU adopted REACH, other countries have developed, or are developing, similar legislation. For instance, on 1 January 2015 Korea's Act on the Registration and Evaluation of Chemicals (ARECs, or sometimes referred to as K-REACH) came into force. Similarly, on 23 December 2017 Turkey's KKDIK law came into effect with similar provisions to REACH. As a number of the substances for which REACH dossiers have been prepared would fulfil the registration requirements in other countries such as Korea and Turkey, significant one-off savings could be realised by companies who notify in the EU and these other countries, thanks, in part, to Mutual Acceptance of Data and the OECD's work on (Q)SARs.

As approximately 21 500 chemicals have been registered under REACH since 2008 and a significant portion of these chemicals will also be registered in Korea and Turkey, the expected one-off savings will be orders of magnitude higher than the annual recurring savings estimated above.

Notes

1. This and all other figures in the report are adjusted for inflation and reflect 2017 currency, unless otherwise specified.
2. A fifth survey was conducted of the pharmaceutical industry; however, due to some inconsistencies in the responses, analysis of this industry has not been conducted for this report. None-the-less, Chapter 3 does include some of the information collected from the pharmaceutical industry.
3. In Tables 2.3, 2.5-2.8 and 2.10-2.11 the savings are presented without taking into account the costs of the EHS Programme (i.e. they do not reflect net savings).
4. Based on the yearly average of 2016-2017.
5. OECD countries agreed to invite Colombia to become a member of the Organisation and Colombia's membership will take effect after it has taken the appropriate steps at the national level to accede to the OECD Convention and deposited its instrument of accession with the French government, the depository of the Convention.
6. That is, for example, if an industrial chemical company conducted tests for a new product and none of those tests were conducted using OECD Test Guidelines and

GLP in an OECD or MAD adherent country, 30% of the tests would have to be repeated, while the remaining 70% would still be accepted.

7. It should be noted that, while some of the assumptions that underpin the estimate of the savings on new and existing industrial chemicals come from the analysis of REACH-generated data rather than from the EHS survey's responses, REACH data provide quite an accurate picture of the situation of the European market and, by approximation, of the other OECD markets. The costs of testing derived from the survey of the industrial chemicals sector was EUR 250 000, thus the statistical test cost used above is a conservative estimate.

8. Based on the EHS survey of industry (2018). See Annex A for details.

9. OECD Guidance for Country Data Review reports (monographs), is available at: www.oecd.org/env/ehs/pesticides-biocides/countrydatareviewreportsforagriculturalchemicalpesticides.htm.

10. Based on the EHS survey of industry (2018). See Annex A for details.

11. Based on RPA's analysis.

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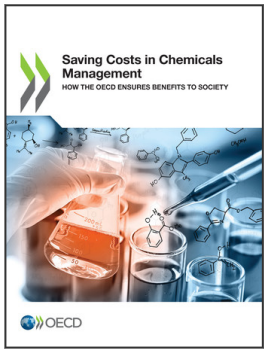

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