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**SAVINGS TO GOVERNMENTS AND INDUSTRY RESULTING FROM THE OECD
ENVIRONMENTAL HEALTH AND SAFETY PROGRAMME**

ENVIRONMENT MINISTERIAL STEERING GROUP

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This document presents the results of a study undertaken by the Environmental Health and Safety Division. It includes a Part I, which gives an executive overview of the results and a Part II which describes in detail how the overall results have been obtained.

The paper is intended as an information document to be distributed with the documentation for the Ministerial Meeting. It supports the paragraphs 33 and 34 of ENV/EPOC/MIN(98)1, Shared Goals for Action.

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SAVINGS TO GOVERNMENTS AND INDUSTRY RESULTING FROM THE OECD ENVIRONMENTAL HEALTH AND SAFETY PROGRAMME

PART I: EXECUTIVE OVERVIEW

INTRODUCTION

From the time of its creation in 1978, the OECD Environmental Health and Safety (EHS) Programme has been premised, and largely justified on the basis of the cost-savings that would accrue to participating Member countries and industry from the practical products generated by the Programme. Evidence of such savings has, to date, been largely anecdotal.

This report presents the results of a first effort to establish actual cost-savings *to governments and industry in OECD Member countries* for those parts of the Programme for which it is possible to make reliable estimations. Even with the quite conservative assumptions employed in the analysis, *the yearly quantified net savings amount to more than FF 320 million*. An accompanying paper (Part II: Support Document) provides the details of the analysis of the costs, savings and non-quantified benefits.

THE CHEMICAL INDUSTRY TODAY

The chemical industry is one of the world's large and fast-growing economic sectors. World production of basic chemicals and chemical products -- including *industrial chemicals, pharmaceuticals, pesticides, food and feed additives and cosmetics* -- reached FF 8,8 trillion in 1996, nearly four times the industry's value three decades ago.

The chemical industry employs approximately 12 million people world-wide. In OECD countries, which account for 78% of world production, chemicals and chemical products represent 14% of total imports and exports of manufactured goods. Chemicals make up as much as 12% of some countries' Gross Domestic Product (GDP).

THE REGULATORY BURDEN

The wide-reaching economic as well as health and environmental consequences of major problems involving chemicals (like the Minamata disease in Japan caused by mercury or the ubiquitous presence of PCB's in man, animals and the environment which causes a variety of anomalies) have convinced everyone that preventing chemical risks is far cheaper than to "react and cure". Neither OECD governments nor the chemical industry would suggest that chemicals be allowed on the market today without being *tested* for potential risks to people and the environment, then *evaluated* and, as needed, *regulated* in an appropriate manner. However, chemical testing and regulation also result in significant costs for the industry, which must carry out the tests, and for national governments, which must evaluate the test results before deciding whether to approve a new product. Safety testing of one new pesticide, for example, costs the industry at least FF 17 million. Evaluating the results can take nearly 3 man-years of government staff time.

These costs are multiplied if different governments impose different requirements -- forcing the, often multinational, chemical companies to conduct additional tests and to prepare a new product "dossier" each time they seek approval to market their product in a different country. In addition, delays in marketing of a new product can lead to an important loss of profit for industry. In the field of

chemicals management, governments therefore have a double responsibility: first they must ensure that products are safe for man and the environment; governments are also bound, however, to make the necessary testing, evaluation and registration process the least burdensome as possible for the industry which has to assume most of the costs.

TRADE ASPECTS

The success of the Uruguay Round of Multilateral Trade Negotiations (concluded in 1994) has reduced tariffs among Members of the World Trade Organisation. Increasingly, non-tariff barriers to trade such as varied testing and regulations become the only remaining impediments to trade. The Economist of 20th May 1997 mentioned that "These days, it is differences in national regulations, far more than tariffs, that put sand in the wheels of trade between rich countries". This emphasizes the importance for trade of international harmonization.

THE ROLE OF OECD

OECD is particularly well suited to work on the development of common tools and policies for chemicals for several reasons. First, as world leaders (78 %) in the production of chemicals, OECD countries have an important global responsibility for the sound management of this industry which includes many large multinational companies. Second, OECD countries have similar markets, populations, per capita GDP, and levels of environmental protection, and this similarity greatly facilitates the development and use of common approaches. Finally, OECD countries are all seeking ways to reduce government spending without compromising economic development, trade or environmental safety. By working together in OECD, governments can ensure that sound management of chemical products is implemented in a way which is most efficient for themselves and for industry. The results of all the work of OECD's EHS Programme are made available world-wide through Internet and by working with UN organisations. Many of the products of the Programme have become, in practice, the world-wide standards.

THE EHS PROGRAMME

The purpose of the EHS Programme is to help OECD governments reduce barriers to trade, optimise the use of their resources, and save time and money for industry by working co-operatively on the testing and evaluation of chemicals, pesticides and the products of biotechnology. The goal is to harmonize national regulatory requirements so as to eliminate "redundant" testing and assessment and enable countries to join forces and divide up the work of chemical evaluation.

The Programme works toward this goal by:

developing policies and instruments for chemical testing and assessment, including test guidelines, principles of good laboratory practice, risk assessment methods, and the contents for chemical dossiers and assessment reports, many of which have been given legal status through OECD Council Acts. The use of these tools by all OECD countries (and others) promotes international harmonization and facilitates product approval in multiple countries.

providing a framework to enable governments to directly “share the burden” of product evaluation (including OECD-wide agreed assessments of high production volume industrial chemicals and development of “consensus” documents to support the assessment of the safety of products of modern biotechnology, such as genetically-modified crops).

providing services to help countries exchange experience and information, and to work co-operatively on the risk assessment and risk management of chemicals and products of biotechnology. These supplement the practical tools by giving OECD countries a forum and mechanism that enable them to work together, discuss new developments, and increase mutual understanding about national and regional regulatory practices.

MUTUAL ACCEPTANCE OF DATA IN THE ASSESSMENT OF CHEMICALS

OECD has developed and maintained a system which harmonises OECD-wide the national regulations related to acceptance by authorities of safety data to be used in the assessment chemicals and chemical products. This system of Mutual Acceptance of Data which is established through three Council Decisions helps to avoid conflicting or duplicative national data requirements, provides a common basis for co-operation among national authorities and avoids the creation of non-tariff barriers to trade. OECD countries have agreed that, when the various safety tests required for registration or notification purposes are carried out in one OECD country in accordance with the OECD Test Guidelines and Principles of Good Laboratory Practice (GLP), the other OECD countries will accept the data for assessment purposes. This saves chemical industry the expenses of duplicative testing for products which are marketed abroad.

The Test Guidelines and Principles of GLP are continuously expanded and updated to bring them to the state-of-the-art of current science. A 1997 Council Decision provides the possibility to non-member countries to adhere to this system and participate in the future development of Test Guidelines and GLP, making the system of Mutual Acceptance of Data accessible to all WTO members. The Test Guidelines and Principles of GLP, which have long been the basis of national technical regulations related to data acceptance in OECD countries, thus fulfil the major WTO requirements for “international standards” of transparency, avoidance of trade barriers and, now, openness of participation by all WTO members.

COSTS, SAVINGS AND NON-QUANTIFIED BENEFITS OF THE EHS PROGRAMME

Methodology

Information on the costs and benefits of the EHS Programme was obtained from Programme records and from government and industry experts who have participated in the various activities. Costs of the Programme were divided into:

Secretariat costs: costs for OECD Secretariat support including staff salaries, benefits and travel; consultants and invited experts; and general overhead; and

Country costs: costs to governments, industry and non-governmental organisations to participate in and contribute to the Programme’s work. These include both travel costs to attend OECD meetings, and staff costs for developing and reviewing EHS documents, preparing for meetings, and attending meetings.

Benefits of the Programme were divided into:

savings: costs saved by having an EHS Programme product (test guideline, chemical assessment report, etc.) that reduces duplicative testing and evaluation of chemicals; and

non-quantified benefits: benefits accrued especially by governments, but also by industry, from the exchange of technical information and policy experience in the OECD forum. In addition to establishing a basis for increased harmonization, this exchange creates a network among countries that provides innumerable -- but not easily quantified -- benefits.

In assessing the savings, *conservative assumptions* were used regarding the number of substances tested, the number of tests required, the costs of the test package, the number of markets to which the substances are introduced, and the percentage of tests that need to be repeated when not done according to OECD guidelines, to ensure that the analysis did not over-estimate savings.

The assessment of non-quantifiable benefits includes only benefits that are related to economic savings. *Health and environmental benefits that result from improved chemicals management obviously are great, but have not been considered here.*

Results

The results of the analysis are summarised in the tables below. Table 1 includes the *costs and savings resulting from* the EHS Programme *for a one-year period*, based on information available for the years 1995-1996 (in some cases, an average of costs for a 2-year period was considered a better indicator of yearly costs than information for just one year). Table 2 gives examples of the Programme's *non quantified benefits*.

Table 1

**YEARLY COSTS AND SAVINGS RESULTING FROM THE OECD EHS PROGRAMME
(ESTIMATED IN FRENCH FRANCS AND ROUNDED OFF)**

Costs to government and industry of participation in EHS Programme	Estimate savings resulting from the EHS Programme to government and industry through the testing, evaluation and approval of different chemical products
Secretariat 18 million	New industrial chemicals 35 million
Countries 39 million	New pesticides 120 million
	New pharmaceuticals 216 million
	High production volume industrial chemicals 10 million
Total:57 million	Total: 381 million
Yearly net savings due to the OECD EHS Programme: 324 million	

Table 2

EXAMPLES OF THE NON-QUANTIFIED BENEFITS OF THE EHS PROGRAMME

Benefits for governments	Benefits for industry
Creation of networks among government and industry experts in the OECD countries	Reduction in non-tariff trade barriers
Forum to develop new policies with a view to harmonization OECD-wide (8 Council Decisions, 12 Council Recommendations)	Reduction in delays for marketing new products
Development of technical instruments that improve the quality of chemical evaluations and regulations	Creation of a level playing field regarding regulations in OECD countries
Access to information and advice from countries with different policy experience	Harmonized classification and labelling systems for chemical products
Harmonized classification and labelling systems for chemical products	Creation of networks among government and industry experts from the OECD countries
Much increased availability of safety data on high production volume chemicals	Opportunity to obtain information about OECD countries' policies and regulations

SAVINGS TO GOVERNMENTS AND INDUSTRY RESULTING FROM THE OECD ENVIRONMENTAL HEALTH AND SAFETY PROGRAMME

PART II: SUPPORT INFORMATION

I. ACTIVITIES OF THE OECD ENVIRONMENTAL HEALTH AND SAFETY PROGRAMME

Background

Production of and trade in chemicals (including industrial chemicals, pesticides, pharmaceuticals and food additives) have increased dramatically over the last three decades; today trade in chemicals represents 14 per cent of total imports and exports of manufactured goods. This growth in production and use of chemicals can lead to an increase in the potential risk they pose. OECD Member countries have responded to this with comprehensive regulatory frameworks. These are based on testing chemicals for potential adverse effects, assessing their risks, and, if necessary, taking measures to prevent or minimise such risks.

While **safety testing of chemicals** is an absolute necessity in view of the protection of man and the environment, it does not come without a cost. Companies spend millions of dollars a year on the testing of chemicals and governments expend thousands of staff hours to evaluate the results. Differences in chemical control policies from country-to-country can lead to waste of resources for industry by **duplication of testing and assessment efforts** and creation of **non-tariff barriers to the trade of chemicals**. In an era of globalisation, with tariffs progressively decreasing, such differences in regulations and (test) standards become an increasingly important remaining barrier to trade. Furthermore, they discourage research, innovation and growth, and increase the time it takes to introduce a new product to the market; and they can also lead to inefficiencies for governments, because authorities cannot take full advantage of the work of others which would help reduce the resources needed for chemicals control.

The OECD Environmental Health and Safety (EHS) Programme assists Member countries in **developing common policies and instruments to guarantee a high level of environmental and health protection, while minimising duplicative work and distortions in trade**. The Programme achieves this dual goal in four ways:

- harmonization;
- sharing the burden; and
- exchange of technical and policy information; and
- outreach.

Harmonization

By harmonizing national approaches to regulations related to chemicals, industry is not faced with a plethora of conflicting or duplicative requirements; governments are provided with a common basis for working with each other; and non-tariff barriers to trade are reduced. The principal tools for harmonization are the OECD Council Decisions related to the **Mutual Acceptance of Data (MAD)** which include the **OECD Guidelines for the Testing of Chemicals** and the **Principles of Good Laboratory Practice (GLP)**. Every year, many companies submit to governments notification or registration applications for thousands of new industrial chemicals, pesticides, pharmaceuticals and food additives.

For many of these chemicals, an extensive set of safety tests is required. But, under the MAD Decisions, when data are developed in one country in accordance with the OECD Test Guidelines and GLP Principles, they are accepted for assessment purposes in all OECD countries. Therefore, a company is spared the added expense of re-testing a substance if it wishes to market that chemical in more than one country; and delays in marketing a new product and distortions in trade are avoided.

Sharing the burden

By working together in tackling chemicals management issues, countries can share the burden associated with this work which they might otherwise have to face alone. Such sharing of the burden saves valuable government and industry resources and gets more work done faster. This is particularly the case with the **evaluation of the safety of high production volume chemicals**. Most of these commodity chemicals are produced and marketed in more than one country. If each country would evaluate the safety of these substances independently, there would be great duplication of efforts. Through the OECD EHS Programme, countries share the burden of investigating these high production volume chemicals. Based on a distribution of workload among countries according to relative Gross Domestic Product, the work of testing and evaluating these chemicals is done co-operatively in OECD. For each substance, a chemical company carries out the necessary testing on a voluntary basis and a government prepares an assessment which is discussed and agreed in OECD. In working this way, considerable resources of government experts are saved; and industry is saved the costs associated with responding to duplicative government demands to carry out safety tests on their chemicals.

Exchange of technical and policy information

The Environmental Health and Safety Programme provides a framework to countries for exchanging technical and policy information. This leads to **greater confidence in, and acceptance of, each other's approaches and ultimately to more efficient and effective chemicals management programmes**. By discussing their chemical control policies together and seeking ways to harmonize instruments and methods, countries tend to develop such policies and regulations in a similar way. Moreover, confidence in each other's systems is built up, leading to a greater acceptance of one another's safety assessments. Government regulators that exchange such assessments can significantly reduce the time and effort needed to approve a new product or register an existing one. In this way, not only are government resources saved, but products can also be brought to market faster.

Outreach

OECD plays a key role in the implementation of **UNCED's Agenda 21, Chapter 19**, on the Sound Management of Toxic Chemicals because its Environmental Health and Safety Programme is the leading international programme in the field. The products of the Programme are used widely by non-member countries and many activities are undertaken (together with UN-organisations) to help non-member countries set up their chemical control systems and to introduce those countries to the principles for chemicals control used in OECD countries. The Programme has prepared many substantial documents for use by the Intergovernmental Forum on Chemical Safety, which was set up by 120 countries to discuss their needs related to the implementation of Chapter 19. The OECD Environmental Health and Safety work related to UNCED is formally co-ordinated with that of other international organisations working on chemical and pesticide safety [FAO, ILO, UNEP, UNIDO, UNITAR and WHO].

The Environmental Health and Safety Programme is looking at ways to engage in its work the emerging major chemicals producing countries outside OECD. The Council has adopted a Council

Decision¹ which **opens up to non-member countries the Council Decisions related to Mutual Acceptance of Data**. In doing so, major chemicals producing non-members can be provided with specific assistance in further developing their chemicals control regulations and frameworks; they will be able to participate in the OECD work on Test Guidelines and GLP; and the Mutual Acceptance of Data system would be extended, so that it would cover an even larger percentage of the global chemicals production.

Pesticides, Pollutant Release and Transfer Registers, Chemical Accidents, Food Safety and Biotechnology

Above some examples have been given of work carried out in the Environmental Health and Safety Programme. Harmonization, sharing the burden or exchange of technical and policy information are also undertaken in many other areas, such as sharing of evaluations of pesticides; the development of guiding principles for chemical accident prevention, preparedness and response; development and harmonization of risk assessment methods; risk management of chemicals and pesticides; assessing the safety of novel foods and development and implementation of Pollutant Release and Transfer Registers. Most recently, at the request of Member countries and industry, a major activity has been initiated to harmonize within OECD the information needed for the assessment of the safety of genetically-modified crops and micro-organisms. For all major new crops produced through modern biotechnology “consensus documents” with internationally agreed information are produced. Again, this ensures that high quality safety information is available, while contributing in a major way to avoid duplicative efforts and non-tariff trade barriers.

EHS Programme Implementation

The main activities the EHS Programme dealt with in 1996 are:

- Testing and Assessment of Chemicals and Pesticides;
- Co-operation on Investigating High Production Volume Chemicals;
- Risk Management of Chemicals;
- Pesticides Management;
- Chemical Accidents Prevention, Preparedness and Response; and
- Harmonization of Regulatory Oversight in Biotechnology.

Implementation of the EHS Programme’s activities relies very much on input from government representatives from OECD countries. However, experts from industry, academia, environmental and consumer organisations, non-member countries, and other international organisations also make important contributions. The daily work of the EHS Programme is co-ordinated and supported by approximately 25 staff members of the OECD Secretariat (supported by the regular OECD budget and extra budgetary contributions from 27 of the 29 Member countries).

¹ Decision of the Council (C(97)114/Final) on Adherence of Non-Member Countries to the Council Acts related to the Mutual Acceptance of Data in the Assessment of Chemicals [C(81)30(Final) and C(89)87(Final)].

II. ESTIMATED COSTS OF THE EHS PROGRAMME

Methodology

It is relatively easy to determine the costs of the EHS Programme, by using information from the OECD Secretariat's records and from government and industry experts who participated in the Programme's work during 1995-1996.

The costs of implementing the EHS Programme involve both **Secretariat** and **country** costs.

Secretariat costs are the costs for the OECD Secretariat support including staff salaries, benefits and travels; consultants and invited experts; and general overhead.

Country costs are the costs to governments, industry and other non-governmental organisations (NGOs) to participate in and contribute to the EHS Programme work. They include both travel costs to attend OECD meetings, and staff costs for (a) developing and reviewing EHS documents, (b) preparing for EHS meetings, and (c) attending EHS meetings.

For the purpose of this analysis, the following baselines were used:

- **Secretariat costs** were based on the Programme budget for 1996.
- **Country staff costs** were based on an average of the years 1995 and 1996 in order to compensate for yearly fluctuations in costs (e.g. those resulting from fluctuations in yearly frequency of meetings). Costs of staff time in countries vary but were assumed to be on the average 200 French francs/hour, based on information obtained in a survey of government and industry representatives. The number of EHS meetings (policy bodies, expert groups and workshops) and the number of staff hours spent in these meetings (number of experts attending and number of days per meeting) were derived from information available in EHS Programme meeting records.
- **Country travel costs** were, like country staff costs, based on an average of the years 1995 and 1996. They were assumed to be an average of FF 5000 for a round-trip ticket plus FF 1000/day per diem (for meals and lodging).

Overall Costs

The estimated costs of the EHS Programme for one year are shown in Table 1.

Table 1

**ESTIMATED TOTAL COSTS (IN FF) TO SUPPORT THE EHS PROGRAMME
(CHEMICALS, PESTICIDES, CHEMICAL ACCIDENTS AND BIOTECHNOLOGY)**

COUNTRY COSTS		SECRETARIAT COSTS	
Number of meetings	58	Part I Budget²	
Average length of meetings ³ (days)	2.21	Expenditure for permanent staff	2,400,000
Total number of participants	1811	Consultancy funds	700,000
Travel costs	13,000,000	Part II Budget⁴	
Country staff costs	26,000,000	Special Programme on the Control of Chemicals	10,700,000
		Grants ⁵	4,400,000
Total country costs	39,000,000	Total Secretariat costs	18,200,000
Total costs (Secretariat and country)		57,200,000	

² The Part I Budget is the regular OECD Budget to which all Member countries contribute.

³ The average length of meetings is a weighted average based on the number of participants and the length of time of each meeting.

⁴ The Part II Budget constitutes assessed extra-budgetary contributions made by 27 out the 29 Member countries to support the Special Programme on the Control of Chemicals.

⁵ Extra-budgetary contributions from countries to support specific activities in the EHS Programme.

III. ESTIMATED SAVINGS OF THE ENVIRONMENTAL HEALTH AND SAFETY PROGRAMME

Background

A part of the benefits of the EHS Programme that accrue to government and industry can readily be estimated in quantified terms because they can be calculated as **savings**. The activities that are most amenable to this are in the area of testing and assessment of new pesticides, pharmaceuticals, and industrial chemicals and the systematic investigation of high production volume chemicals. Other activities within the EHS Programme can only be described, at this time, in non-quantified terms. This is either because the benefits are not easy to measure in direct monetary gains, or the activities are still relatively new and the results have not been implemented for sufficient time to gauge impact. **It should not be inferred, however, that non-quantified benefits are less real, less likely to occur, or less important than the quantified benefits.**

A. SAVINGS

BOX 1: A STORY FROM INDUSTRY

Prior to the 1981 Council Decision on Mutual Acceptance of Data, Japan required that reproduction toxicity studies and chronic toxicity studies for the registration of new drugs in Japan be performed in Japan itself, irrespective of data already available from studies done in other countries. After the implementation of the 1981 Council Decision, this requirement was abolished. This led to significant cost-savings to pharmaceutical companies which previously had to establish their own facilities in Japan or had to pay a Japanese contract laboratory to repeat studies in Japan. Since these two types of studies cost approximately FF 10,000,000 for a new pharmaceutical product, one could multiply the number of new drugs of foreign origin registered in Japan since 1983 (i.e. 284) times FF 10,000,000 to get an estimate of savings to industry (FF 2840 million), or FF 200 million/year. (Source: pharmaceutical industry regulatory affairs officers)

Methodology for Quantifying the Savings

As stated above, one of the principal values of the EHS Programme is that it helps to reduce duplication of work for industry and governments. The potential for such duplication is great, given the international character of the chemicals, pesticides, pharmaceuticals, food and feed additives and cosmetics industry where products are developed for and sold in multiple markets. To calculate the extent to which OECD work helps to avoid such duplication, several **assumptions** were made.

- First, based on discussions with government and industry experts, it is reasonable to assume that each (often multinational) company which conducted safety testing and notified or

registered a **new** industrial chemical, pesticide, pharmaceutical or food additive into one market in 1996, also did this in other markets in OECD. For the purposes of this report, the 29 OECD countries are generally not considered individually, but rather as part of three major regional markets: North America, Europe and the Asia/Pacific region. It was assumed that for each new product notified or registered in one region, this was also done in two other regions.

- Second, after **new** substance clearance in one market, a company would have to repeat a considerable part of the testing to obtain such clearance for subsequent markets, in order to comply with different requirements in other countries were it not for the availability of OECD Test Guidelines (TG) and Good Laboratory Practice (GLP) and the system for the Mutual Acceptance of Data as established in two OECD Council Decisions^{6, 7}. One cannot assume that if OECD TG/GLP did not exist, country A would not accept any of the data generated in country B. It is assumed that without OECD, test methods would have been developed by countries independently and that these would not have been exactly the same among countries. It seems likely, however, that Country A would have accepted a part of the data developed using Country B's different methods. Based on discussions with experts in governments and industry, it is estimated that 30% of the foreign test data would not be accepted because of differing methods and testing would have to be repeated. This is a conservative estimate which assumes that 70% of the data would be accepted in a second country, even if such data would not fully conform with the requirements of that country⁸.
- Third, as for chemicals **already on the markets**, OECD records show that each industrial chemical produced in high volumes in one country is also produced or imported in high volumes by industry in an average of two other countries which would eventually want to assess its safety. The specific assumptions made with respect to the availability and acceptability of data in high production volume chemicals which are already on the market have been described in Annex 2.

Harmonization of Testing and Assessment

No Repeat Testing

Each year, industrial chemical, pesticide, pharmaceutical and food additive manufacturers report to governments their intention to manufacture and market hundreds of new substances. This is accompanied by a set of test data to allow an assessment regarding the safety of the chemical to be made. The tests that need to be done can be simple and inexpensive (e.g. determination of a melting point which costs around FF 2200); but others are complicated and expensive (e.g. FF 2,500,000 to determine long-term toxicity and carcinogenicity effects in mammals). The number of tests required for a risk assessment varies depending on the type of product under consideration. Testing to generate a base-set of safety data for new industrial chemicals typically costs around FF 800,000; whereas pesticide and pre-clinical

⁶ Decision of the Council concerning the Mutual Acceptance of Data in the Assessment of Chemicals C(82)30(Final) and 9 Addenda

⁷ Decision-Recommendation of the Council on Compliance with Principles of Good Laboratory Practice C(89)87(Final)

⁸ Chemical industry experts estimate that 50 % of the tests need to be repeated

pharmaceutical testing (for which OECD Test Guidelines exist) are estimated to cost approximately FF 17,000,000 and FF 10,000,000 respectively (see Annex 1).⁹

Having to repeat tests for each new market could be a significant obstacle to trade in chemicals. By using OECD Test Guidelines and GLP, a company can be assured that its test data will be accepted by governments for their assessment purposes throughout OECD as a result of the Mutual Acceptance of Data system. As can be seen from Table 2, this approach has saved industry a significant amount of resources for products which are introduced in multiple markets.

Table 2

ESTIMATED SAVINGS (IN FF) DUE TO MUTUAL ACCEPTANCE OF DATA FOR NEW PRODUCTS

	New Industrial Chemicals	New Pesticides	New Pharmaceuticals	TOTAL
Average number of substances introduced in each of the three major regions of OECD (Asia/Pacific, North America, Europe) in 1996 (for details, see Annex 1)	74	10	36	
Cost of testing per chemical	800,000	17,000,000	10,000,000	
Total cost of testing across all three regions <u>without</u> Mutual Acceptance of Data¹⁰	94,720,000	272,000,000	576,000,000	
Total cost of testing across all three regions <u>with</u> Mutual Acceptance of Data¹¹	59,200,000	170,000,000	360,000,000	
1996 savings due to OECD EHS Programme	35,520,00	102,000,000	216,000,0000	353,520,000

⁹ The European Crop Protection Association (ECPA) estimates that the total costs spent on toxicology on environmental science in the development of a pesticide amounts to FF 365 million. The estimate of FF 17 million for tests to be done according to OECD Test Guidelines is very conservative

¹⁰ (Number of substances) x (cost of testing) + 2 x [30% x (Nr of substances) x (cost of testing)]

¹¹ (Number of substances) x (cost of testing)

Harmonization of Industry Dossiers for Pesticides Registration

Over the past few years, the OECD Pesticide Programme has worked on ways to improve the efficiency of pesticide (re-)registration and reduce the cost to industry and governments involved in the pesticide approval process. Given the extensive experience of governments and industry with pesticide registration, it is possible to estimate the current costs associated with such work, and the extent to which these costs could be reduced if greater co-operation among countries in sharing data and assessments occurred in the future.

One approach to reducing time and effort needed for pesticide (re-)registration is harmonizing the formats in the registration dossiers used by industry to submit data so that once a company compiles its first dossier for one country, the cost and time to develop dossiers for other countries will be significantly reduced. The pesticide industry has estimated that this saves as much as 60% of the total cost of FF 700,000 per pesticide for preparing a dossier (cost of testing not included).¹² It is estimated that cost of preparation of a dossier for two additional regions is for each region 75% of the cost of the first one. Assuming that 10 new pesticides enter the market each year, the savings to industry for dossier development are therefore estimated at FF 4,900,000 per year (see Table 3).

Table 3

ESTIMATED SAVINGS (IN FF) TO INDUSTRY RESULTING FROM HARMONIZED INDUSTRY DOSSIERS FOR PESTICIDE REGISTRATION

Number of new pesticides to be registered	10
Cost to prepare one dossier	700,000
Total cost to prepare dossiers for all new pesticides across all three regions <u>without</u> OECD harmonized dossier¹³	17,500,000
Total cost to prepare dossiers for all new pesticides across all three regions <u>with</u> OECD harmonized dossier¹⁴	12,600,000
Yearly savings due to OECD EHS Programme	4,900,000

Harmonization of Country Review Reports

Just as harmonizing the format used in industry registration dossiers will significantly reduce costs and time (for both industry and governments), harmonizing the formats of country review reports also provides substantial benefits by facilitating the sharing of such information. Governments would save resources if they could use other countries' review reports to support their own decision-making.

¹² Source: European Crop Protection Association

¹³ $(10 \times \text{FF } 700,000) + 10 \times 525,000$ (second dossier costs 75% of the original one) $\times 2$ (Regions)

¹⁴ $(10 \times \text{FF } 700,000) + 40\% (1 \times 700,000 \times 2)$

The Pesticide Programme has addressed the harmonization of the format for country reports. Based on information from experts in EU member states, reviewing a full industry dossier on a new pesticide and writing a comprehensive report takes approximately 2.7 man years. However, if another country's review of the same pesticide could be used, these experts estimate that 2 full man years of time are saved. This results in significant savings as can be seen from Table 4

Table 4

**ESTIMATED SAVINGS (IN FF) TO GOVERNMENTS DUE TO
HARMONIZED COUNTRY REVIEW REPORTS**

Number of new pesticides	10
Cost to review one dossier¹⁵	864,000
Total cost to review dossiers on all new pesticides across all three regions <u>without</u> OECD harmonized report format¹⁶	25,920,000
Total cost to review dossiers all new pesticides across all three regions <u>with</u> OECD harmonized report format¹⁷	13,120,000
Predicted yearly savings due to OECD EHS Programme	12,800,000

Sharing the Burden

Limiting the Costs of Testing and Assessing High Production Volume Chemicals

World-wide, there are approximately 100,000 chemical substances in commerce. For most of these chemicals, no systematic safety evaluation has been undertaken. Member countries have recognised in a Council Act the need to evaluate systematically the safety to man and the environment of chemicals already in use¹⁸. This could be a daunting task if countries were to look at all of the chemicals which are now on the market and if they were to undertake this task independently of other countries. Fortunately, exposure to most chemicals is rather limited as most are used in very small amounts¹⁹ (some 1,500 cover over 95% of total world production). Based on that fact, the OECD Existing Chemicals Programme focuses on investigating those chemicals produced or imported in large volumes in Member countries (at

¹⁵ 2.7 man years = [8 hours/day x FF 200/hour x 200 days/year x 2.7 man-years] = FF 864,000

¹⁶ FF 864,000 x 10 new pesticides x 3 regions = FF 25,920,000

¹⁷ 0.7 man years = [8 hours/day x FF 200/hour x 200 days/year x 0.7 man-year] = FF 224,000
10 dossiers x 864,000 (first region) + 2 x 10 dossiers x 224,000 = FF 13,120,000

¹⁸ Decision-Recommendation of the Council on the Systematic Investigation of Existing Chemicals [C(87)90(Final)]

¹⁹ The United Nations Conference on Environment and Development; Agenda 21, Chapter 19, section 19.11

least 1000 tonnes per year in one country), the so-called High Production Volume (HPV) chemicals. Many of the HPV chemicals are being produced by several, often multinational companies, and are on the market in many of the OECD countries. OECD Member countries decided through a Council Act to investigate the HPV chemicals co-operatively²⁰. Each year, the tasks of investigating a number of HPV chemicals are distributed among Member countries²¹ in order to gather the existing information, undertake the necessary testing²², conduct a risk assessment to determine the potential risks of the chemicals and to identify if there is a need for further investigations or risk management. The testing is undertaken by industry on a voluntary basis; the assessment is discussed and agreed in OECD by all Member countries, resulting in “co-operative assessments”.

By sharing the burden in this way, it is not necessary for every country to assess each HPV chemical that it imports or produces. Rather, the work is divided among countries and the results of the co-operative work can be used by all countries for national decision-making purposes. In addition, the necessary testing to complete the data set needs only to be done by one company in one country; this avoids several companies having to address, at high costs, differing requirements related to testing of their HPV chemicals in a number of countries.

BOX 2: SHARING OF THE BURDEN IN PRACTICE

Distribution of the burden of investigating high production volume chemicals over countries is done according to relative Gross Domestic Product. For example, for a sample of 100 chemicals, this would mean in practice that by investigating three chemicals, a country like Austria gains access to internationally agreed assessments on 97 more chemicals within the same time period. Even the United States, with an obligation to investigate 25 of the 100 chemicals, receives the data and reports on 75 others for which the testing resources of US industry and assessment resources of the US government are saved. No attempt has been made to quantify these very significant savings.

In 1996, assessments were finalised on 31 substances in the OECD Programme. For 19 of these substances, existing data had been insufficient to complete initial assessments and additional testing was required. Since the resulting data sets were found to be acceptable to all Member countries and agreement was reached on the assessments, these are used throughout OECD for decision-making on chemicals management. Analysis of the OECD List of HPV chemicals shows that, on average, chemicals selected for investigation in the Programme are usually produced or imported by different companies in high volumes in more than two other countries. The savings to industry on the costs of testing are calculated based on the assumption that partial re-testing in two other countries can be avoided (see Table 5).

²⁰ Decision-Recommendation of the Council on the Co-operative Investigation and Risk Reduction of Existing Chemicals [C(90)163/FINAL]

²¹ The distribution of chemicals over Member countries is done in accordance with their relative Gross Domestic Product

²² It was agreed by countries that a minimum package of data (the Screening Information Data Set - SIDS) which would allow an initial risk assessment to be made, should be available for each HPV chemical.

Table 5

**ESTIMATED 1996 SAVINGS (IN FF) TO INDUSTRY DUE TO
THE OECD-WIDE ASSESSMENT OF HPV CHEMICALS**

Number of HPV chemicals reviewed	31
Total cost of testing necessary to complete assessments in three countries <u>without</u> OECD Programme²³	20,573,120
Total cost of testing necessary to complete assessments <u>with</u> OECD Programme²⁴	12,858,200
Savings due to OECD EHS Programme	7,714,920

Table 6 describes the benefits for governments of being able to do one single assessment and using a single assessment per chemical. Two scenarios are presented: one in which OECD countries conduct initial assessments independently (assuming three countries would assess the same substance in the context of their own systematic investigation of existing chemicals), and the other in which countries share the burden under the Existing Chemicals Programme. The overall savings to Member governments is FF 1,946,600.

Table 6

**ESTIMATED 1996 SAVINGS TO GOVERNMENTS BY SHARING THE BURDEN
OF ASSESSMENTS OF HPV CHEMICALS**

Number of HPV chemicals reviewed	31
Cost of conducting assessments <u>without</u> OECD HPV Programme²⁵	2,362,000
Cost of conducting assessments <u>with</u> OECD HPV Programme²⁶	415,400
Savings due to OECD EHS Programme	1,946,600

²³ Cost for testing, based on real testing needs for 31 substances plus twice 30% of the costs for testing 31 substances (See Annex 2)

²⁴ See Annex 2.

²⁵ 67 (hours to prepare SIDS dossier and SIDS Assessment Report) x FF 200/hour = 13,400+ 60 (6 hours for national peer review by 10 national experts) x FF 200/ hour = FF 25,400

25,400 x 31 substances x 3 countries = FF 2,362,200

²⁶ [Sponsor country time (FF 13,400) x 31 substances]= FF 415,400 Time for peer review in Member countries would be: 31 substances x [(15 OECD countries who participate in Programme and review assessments) x 6 (hours to review each assessment) x FF 200/Hour] = FF 558,000. This amount is not counted here because it is already included as part of the country costs of the EHS Programme as part of the costs for review of documents in preparation for meetings.

An added advantage of this work is that a much wider universe of information (often unpublished information from industry files) is made available for making the assessment than would be if a country worked alone. An OECD database (EXICHEM) which tracks all work in Member countries related to information gathering, testing, assessment and management of chemicals (i.e. who is doing what on which chemical) provides a basis for countries to seek further (bilateral) co-operative activities.

B. NON-QUANTIFIED BENEFITS

The following gives some examples of benefits of the EHS programme that have not been quantified

New industrial chemicals

Like the Pesticide Programme's efforts to improve the pesticide registration process, the EHS New Chemicals Programme is now also focusing on ways to reduce cost to industry and governments involved in the notification of new industrial chemicals. Confidentiality issues have, for a long time, precluded exchange of assessment reports among governments. Now that more experience with chemical notification systems exists, governments and industry are working together in OECD to find solutions for exchange procedures which respect modern confidentiality requirements. While this work has just begun, it is expected that in the near future, significant benefits will be reaped by avoiding duplication of work related to preparing assessments in industry and evaluating assessments in governments.

Harmonization of Chemical Classification and Labelling

Having different chemical regulatory requirements across countries imposes a considerable burden on the international chemical industry. Differences from country-to-country in the way a product can be packaged, handled, transported, used and disposed of adds significantly to the cost of the final product. The main reason for this is that countries use different systems to classify and label chemicals.

The major international organisations responsible for the sound management of chemicals have launched a programme on the Harmonization of Classification and Labelling Systems, with OECD as the lead organisation for the technical work related to developing human health and the environmental classification criteria. A globally harmonized classification and labelling system, by its nature, would remove non-tariff barriers to trade in chemical substances. It would thus facilitate the exchange of goods at less cost for industry (no difference in packaging requirements, no need to re-label at borders, no different transport conditions) and governments (considerably less costs with respect to administrative, control and enforcement mechanisms).

BOX 3: TRAINING OF GLP INSPECTORS

Training of inspectors for national GLP compliance monitoring programmes, as called for in the 1989 Council Decision-Recommendation on Compliance with GLP, is very expensive for small countries with few inspectors. OECD training courses not only increase harmonisation of inspection procedures among countries but also lead to major savings to small countries.

Development of Risk Assessment and Management Methods

By pooling resources, OECD countries are developing methods for improving the way risk assessments are conducted which will, in turn, lead to better risk management decisions. Ongoing work in this field addresses, for example, the assessment of the safety of novel foods, the assessment of effects of chemicals on terrestrial systems, evaluating the safety of substances that are difficult to test due to their chemical nature and methods to predict the toxic effects of chemicals without testing in animals (e.g. using computer models to relate chemical structure and toxicity). Other projects are aimed at harmonizing among countries the terminology used in risk assessments and developing models to better predict possible exposures to workers, the general population and the environment.

The EHS Risk Management Programme is examining various approaches used by countries and industry to manage risks of chemicals in order to identify those that work well and that may be of use to others. One area of focus has been on how governments and industry, working together, can develop non-regulatory initiatives. Another area of focus is the review of the methods used by governments to assess the costs and benefits of risk management measures. Results of this work should contribute to improve the effectiveness and efficiency of Member countries' risk management programmes.

Another example from the Risk Management Programme concerns the work undertaken on five substances of concern in Member countries (lead, mercury, cadmium, methylene chloride and brominated flame retardants). For each substance, a comprehensive "status report" was published describing the commercial and environmental life-cycles of these products, along with descriptions of how OECD Member countries perceived the risk posed by these substances and what actions they had taken to mitigate these risks. Users of these monographs, both OECD and non-member countries, are able to review various approaches that had been tried, and often, the effectiveness of such approaches. This allows a country considering possible risk management approaches to learn from the experiences of other countries in developing the most effective and efficient national strategy.

All OECD countries can benefit from the shared development of risk assessment and management methods; some of the best and most experienced experts across OECD participate in the work. Individually, no country could match this level of expertise in each field. However, by working together, they have access to high-quality material in many different areas of technical expertise which are respected world-wide. In addition, the costs of developing comprehensive and technical documents individually would be a heavy burden, particularly on smaller countries.

Harmonization of Regulatory Oversight in Biotechnology

The field of biotechnology is becoming increasingly important in agricultural production. Over 40 types of crop plants are currently being modified to exhibit various traits, including insect resistance, herbicide tolerance, disease resistance and several different types of quality characteristics. Each crop plant and trait combination developed by a company is a new product. In the absence of an internationally harmonized approach for commercial approvals, each company is required to obtain approval for each new product in each country in which it wants to market its product. As with chemicals, pharmaceuticals and pesticides, the cost to industry to prepare dossiers, and to governments to review each application, could be substantial. One company has estimated that costs for regulatory approval of an individual product in a country can be around FF 1,750,000. If the product was considered a plant-pesticide, an additional FF 2,500,000 would be required.

A considerable portion of the costs of product approval goes into conducting environmental risk assessments which examine three aspects of the product: its biology, the specific trait introduced (e.g., virus resistance), and the impact on the environment. Since information requested on the biology and trait characteristics remain, to a large extent, the same from country-to-country, countries working together in the EHS Programme are developing “consensus documents” that contain the agreed information for use in the assessment throughout OECD countries (and also in non-member countries).

Thousands of genetically modified crops are currently undergoing field testing, each requiring a separate notification in each country; these field tests represent over 100 different combinations of plants and traits. With the commercialisation potential for genetically modified products growing each year, the use of OECD consensus documents should lead to significant savings for government and industry and also accelerate assessment of these products. The EHS Programme also has developed a database which includes information on the ongoing field testing and commercialisation of genetically-modified products in OECD countries, and information on regulatory developments. This BIOTRACK database is available on Internet and is consulted thousands of time a month by government and industry experts dealing with modern biotechnology to help them in their daily work.

Level Playing Field: Chemical Accidents

The Chemical Accidents Programme has developed some of the most widely used documents produced by the EHS Programme. The OECD Publication on the “Guiding Principles for Chemical Accident Prevention, Preparedness and Response” is one example. This document, the result of a number of technical workshops attended by hundreds of experts, sets out general and specific guidance for the safe planning, construction, management, operation and review of safety performance of hazardous installations. This was the only document ever produced on this topic; it is widely distributed, translated and accepted as an authoritative reference document by both industry and governments inside and outside OECD alike. It is the basis of a Council Recommendation²⁷. This work contributes greatly to development of national policies for chemical accidents prevention, preparedness and response which are similar, leading internationally to a level playing field for industry.

Animal Welfare

Already in 1982, the second High Level Meeting of the Chemicals Group and Management Committee of the OECD Special Programme on the Control of Chemicals concluded that: “the welfare of laboratory animals is important; it will continue to be an important factor influencing the work on the OECD Chemicals Programme”. That meeting further agreed that: “every effort should be made to discover, develop and validate alternative testing systems”. Subsequently, animal welfare issues in general and the reduction, refinement and replacement of animals in OECD Test Guidelines in particular, are recognised as a special activity within the EHS Programme and given considerable weight in the discussions on Test Guidelines development.

Apart from the development of specific *in vitro* tests, the Programme also produces Guidance Documents on animal welfare issues, develops internationally agreed criteria for the validation and acceptance of alternative tests and provides a mechanism for objective and independent review of projects aimed at the replacement of animals in risk assessment. All these activities significantly contribute to the reduction in the use of animals.

²⁷ Recommendation concerning Chemical Accident Prevention, Preparedness and Response [C(92)1/Final].

More importantly, however, is the significant benefit derived also in this respect from the mutual acceptance of data concept which minimises the need for repeat testing and therefore also limits the unnecessary use of test animals.

IV. CONCLUSIONS

As indicated in Table 1, the total costs of the Environmental Health and Safety countries (Secretariat cost and costs for experts from countries and industry for attending and preparing meetings and for reviewing and writing documents) are estimated at FF 57 million per year. A conservative estimate of the overall quantified savings from the Programme (see Table 7) is FF 380 million per year, making a total of **estimated net savings for the Programme of almost FF 324 million per year.**

Table 7

OVERVIEW OF ESTIMATED COSTS AND SAVINGS OF THE EHS PROGRAMME QUANTIFIED IN THIS REPORT IN (FF)

SAVINGS DUE TO:	See Table	SAVINGS	TOTAL
• NEW CHEMICALS			
→ no repeat testing	2	35,520,000	35,520,000
• NEW PESTICIDES			
→ no repeat testing	2	102,000,000	
→ harmonized dossiers	3	4,900,000	
→ harmonized reports	4	12,800,000	
			119,700,000
• NEW PHARMACEUTICALS			
→ no repeat testing	2	216,000,000	216,000,000
• HIGH PRODUCTION VOLUME CHEMICALS			
→ saving on testing	5	7,714,920	
→ saving on assessments	6	1,946,600	
			9,661,520
TOTAL SAVINGS			380,881,520
COSTS	1		- 57,200,000
NET SAVINGS			323,681,520

Not all benefits have been quantified in the report: **such non-quantified benefits undoubtedly exist however and they are not less real, less likely or less important than the quantified benefits.** In some cases, the required data could only have been collected with great difficulty and in others, savings would have been difficult to substantiate; savings are also not calculated for benefits that are expected to be realised in future years. Some examples of work which leads (or will lead) to non-quantified benefits are:

- harmonization of classification and labelling;
- exchange of assessment reports on new chemicals;
- development of methods, for risk assessment and management;
- creating a level playing field throughout OECD with respect to regulations concerning chemical accident prevention, preparedness and response;
- developing “consensus documents” of information that is accepted OECD-wide for use in the assessment of the safety of genetically modified crops and micro-organisms.

Estimates of costs are based on budget data and extensive information on time spent by experts from Member countries and industry and should be quite accurate. As has been stated in the report, a number of assumptions had to be made in particular for the calculation of savings. It should be noted, however, that in all cases **the most conservative option** of the various estimates obtained from industry and government experts has been chosen to calculate the savings. This applies to:

- the number of substances that need to be tested;
- the number of tests that need to be done for each chemical;
- the costs of a test package;
- the number of markets to which a new product is introduced; and
- the percentage of tests that need to be repeated.

In view of this, the number of FF 323 million for the net savings should be considered as a minimum estimate.

Not included in the considerations are benefits industry accrues due to avoiding delays in marketing of new products, which according to industry sources could represent similar amounts of money as those saved by avoiding duplicative testing (for example, when delays in registrations of a pesticide might lead to missing sales for a full growing season). **Not** included in the calculation is also the information that has been obtained from industry on an anecdotal basis (e.g. Box 1).

ANNEX 1

BASIS FOR ESTIMATING THE COSTS OF TESTING OF NEW INDUSTRIAL CHEMICALS, PESTICIDES AND PHARMACEUTICALS REGISTERED IN 1996**Costs of Tests**

OECD's 1982 Council Decision on the Minimum Pre-marketing set of Data (MPD)²⁸ requires that sufficient data be available to ensure that an adequate first assessment of the potential risk to man and the environment can be made before an industrial chemical enters the market. An accompanying Recommendation elaborates the data components and provisions for application of the OECD MPD. This list of data components provides the basis for most of the requirements of new industrial chemical notification and assessment schemes in Member countries. There are some differences from country-to-country, however, in the actual data requirements, e.g. either before manufacturing or before marketing, and in minimum production volume thresholds that trigger requirements for certain data submissions. For example, the EU and Japan require, before marketing, the testing of new industrial chemicals once they have exceeded a certain production threshold; the US, which requires notification before manufacturing, requires testing if there are concerns about the risk posed by the chemicals (often when it reaches a higher production volume) and additional data are needed to complete the assessment.

Based on discussions with industry, contract laboratories and government representatives, it is possible to give a general picture of the tests required by countries for new chemical assessments and the costs for each.

Table 8 provides examples of typical costs to conduct various tests using OECD Test Guidelines and Good Laboratory Practice (GLP). This list does not include all tests for which OECD Test Guidelines exist.

Table 8

Typical Costs for Testing of Substances According to Some of the OECD Test Guidelines and Principles of GLP (Costs in FF)²⁹	
<i>Mammalian Toxicity</i>	<i>Physical-Chemical Properties</i>
Acute oral toxicity.....14,200	Melting point/melting range..... 2200
Acute dermal toxicity..... 22,800	Boiling point/boiling range 2450
Acute inhalation toxicity..... 71,250	Density/relative density 2100
Repeated dose oral toxicity..... 259,200	Vapour pressure.....10,700
Repeated dose oral toxicity with reproductive/developmental screen..... 774,650	Partition coefficient octanol/water..... 17,450
Reverse mutation assay (Ames assay) 29,800	Water solubility.....17,200
In vivo cytogenetics-micronucleus assay..... 174,100	Dissociation constant in water 7,250
In vitro mammalian cytogenetics..... 73,450	Soil adsorption/desorption isotherm..... 97,350
Developmental toxicity test 396,200	<i>Ecotoxicity</i>
Reproduction and fertility effects 2,128,650	Fish acute toxicity.....54,750
Chronic oral toxicity 1,623,000	Aquatic invertebrate acute toxicity..... 36,150
Carcinogenicity.....2,695,000	Algal toxicity.....44,150
	Aquatic invertebrate life-cycle toxicity test..... 132,000
	<i>Environmental Fate and Pathways</i>
	Hydrolysis as a function of pH.....45,700
	Aerobic aquatic degradation.....50,150

²⁸ Decision concerning the Minimum Pre-Marketing Set of Data in the Assessment of Chemicals[C(82)196(Final)]

²⁹ In converting costs of testing from information in US dollars to French Francs, a low exchange rate of 5 FF for one dollar was used in order to not overestimate costs and resulting cost savings

In general, the total cost for typical “base set” testing for a new industrial chemical (according to OECD Test Guidelines) ranges from FF 700,000 to FF 1,000,000. Pre-clinical testing for pharmaceuticals ranges from FF 10,000,000 to FF 15,000,000 and pesticide testing costs, on average, around FF 17,000,000, both when OECD Test Guidelines and GLP are used.

The costs used for purposes of this report, are estimated conservatively and are as follows (Table 9).

Table 9

ESTIMATED COSTS FOR REGISTRATION OF NEW PRODUCTS

	Cost of testing using OECD TG/GLP (FF)
New industrial chemicals	800,000
New pesticides	17,000,000
New pharmaceuticals	10,000,000

Number of Registrations in 1996

A breakdown of the estimated number of new substances that were registered in OECD countries for which data were available in 1996 is provided in Table 10. In order to allow a comparison of benefits to be made for the same year, it is assumed that each chemical introduced in one of the three regional markets (Asia/Pacific, North America and Europe) in 1996 will eventually also be introduced in the remaining two regions. Even though a chemical may have been developed and approved in region A in 1996 (as a “domestic” substance) and also approved in the region B in 1997 (as a “foreign” substance), both would be counted in 1996. It is assumed that, by not counting in 1996 the “foreign” notifications of substances notified domestically in earlier years, the distribution of registrations over time will even out, since the number of new chemical notifications is not changing much over a period of 3 years.

Table 10

NUMBER OF NEW SUBSTANCE NOTIFICATIONS IN 1996

	New industrial chemical notifications requiring base set testing (typically >1 tonne)	New pesticide registrations	New pharmaceutical approvals
EU	100 ³⁰	10 ³¹	36 ³²
Switzerland	13 ³³	“	“
Canada	28 ³⁴	“	“
US	74 ³⁵	“	“
Australia	33 ³⁶	“	“
Japan	194 ³⁷	“	“
Average number of new substances notified in each of the three major regions of OECD (Asia/Pacific, North America, Europe)	74³⁸	10	36

While there are relatively good data on the number of new industrial chemicals notifications in 1996, the number of substances for which testing was required was not always available and had to be estimated or inferred from other sources. For this report, the total number of new industrial chemicals notifications was obtained by adding the total number of notifications in the six countries for which information is available and dividing this by six.

³⁰ Estimate based on response to OECD Survey on international notifications; and EC presentation at OECD Workshop on New Industrial Chemicals.

³¹ World-wide, it is estimated that 10 new pesticide active ingredients are registered each year.

³² Number of new molecular entities launched on to the world market in 1996 (Centre for Medicines Research International).

³³ 1996 Swiss Report on New Chemical Notification; 64 notifications, it is estimated that 20% (or 13) have production volume of >1 tonne.

³⁴ Estimate based on response to OECD Survey on international notifications.

³⁵ 5% of the pre-manufacture notifications require base set type testing; for the 1471 notifications in 1996, this amounts to 74.

³⁶ Number of “standard” notifications received (1993-94); “The Operation of the Industrial Chemicals (Notification and Assessment Act 1989)”.

³⁷ Number of “standard” notifications received (1993-94); “The Operation of the Industrial Chemicals (Notification and Assessment Act 1989)”.

³⁸ Assumes the average across the 6 countries represented in the Table is, at a minimum, the average found among the three major regions of the OECD.

It is important to note that the number of notifications presented in Table 10 is based on conservative estimates. For example for new industrial chemicals, if one just looked at the three major countries (groups of countries) (the US, Japan and the EU), the average number of new substances notified would be much higher than 74 (i.e., 122). But, as data were available for other countries, they were included. Similarly, ten new pesticide registrations is probably a low estimate. Typically after a pesticide active ingredient is approved, pesticide products which could include this ingredient must be tested and registered. Because many products can be developed using the same active ingredient, the actual number of pesticide product registrations is considerably higher than the 10 new ingredients. The 36 pharmaceuticals launched in 1996 is a conservative number too, since it represents only new chemical entities registered. This number does not include metabolites and esters of existing compounds and new combinations of products for which also testing could be required.

ANNEX 2

**BASIS FOR ESTIMATING THE COSTS AND SAVINGS OF
TESTING HPV CHEMICALS CO-OPERATIVELY**

In 1996, 19 of the 31 HPV chemicals for which a systematic investigation was undertaken required additional testing. The tests conducted and the costs for each are given in Table 11.

Table 11

**TESTS UNDERTAKEN ON THE 31 SIDS CHEMICALS
WHICH WERE ASSESSED IN 1996.**

Test undertaken	Unit cost (FF)	Number of HPV chemicals tested	Total cost (FF)
1. Physical-chemical			
Melting point	2200	1	2200
Boiling point	2450	2	4900
Vapour pressure	10,700	7	74,900
Partition coefficient	17,450	7	122,150
Water solubility	17,200	3	51,600
Sub-total			255,750
2. Environmental fate			
Photodegradation	47,500	7	332,500
Hydrolysis	45,700	9	411,300
Biodegradation	50,150	5	250,750
Sub-total			994,550
3. Ecotoxicity			
Acute toxicity to Fish	54,750	3	164,250
Acute toxicity to Daphnia	36,150	1	36,150
Chronic toxicity to Daphnia	132,000	6	792,000
Acute toxicity to Algae	44,150	9	397,350
Sub-total			1,389,750
4. Toxicity			
Gene mutation	29,800	5	149,000
Chromosomal aberration	73,450	7	514,150
28-d Repeated dose	259,200	1	259,200
Repeated Dose/Reproduction Screening	774,650	12	9,295,800
Sub-total			10,218,150
TOTAL			12,858,200

These 31 chemicals are produced or imported on the average by companies in two other countries. Were each of these countries to undertake independently the investigation of these chemicals, one of two assumptions could be made: i) either the industry is aware of previous efforts in one of the other countries and requests the data from its competitor (at a cost which is less than doing the testing) and the country accepts all of the existing data, or ii) there is no contact among competitors or countries doing the assessments and all of the necessary data must be generated independently three times. Since neither of these assumptions reflects the reality, based on discussions with government and industry experts, 30 % has been used as a conservative estimate for the amount of repeat testing that has to be done. This is reflected in Table 5.

Based on experience over the last five years with the systematic investigation of HPV chemicals, the year 1996 can be considered to be representative for other years. There are currently 349 chemicals in the Programme; 109 assessments have been completed to date.