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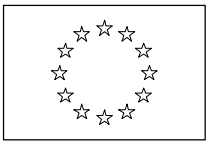
from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	12 July 2006
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	REACH - REVISED LEGISLATIVE FINANCIAL STATEMENT (Based on the political agreement on a common position reached by the Council on 13 December 2005. This legislative financial statement replaces the legislative financial statement presented by the Commission in conjunction with the 'REACH' proposal COM(2003)644) - Commission Staff Working Document

Delegations will find attached Commission document SEC(2006) 924.

Encl.: SEC(2006) 924



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 12.7.2006
SEC(2006)924

COMMISSION STAFF WORKING DOCUMENT

REACH REVISED LEGISLATIVE FINANCIAL STATEMENT

(Based on the political agreement on a common position reached by the Council on 13 December 2005. This legislative financial statement replaces the legislative financial statement presented by the Commission in conjunction with the 'REACH' proposal COM(2003)644)

{COM(2006)375 final}

COMMISSION STAFF WORKING DOCUMENT

REACH REVISED LEGISLATIVE FINANCIAL STATEMENT
(Based on the political agreement on a common position reached by the Council on 13 December 2005. This legislative financial statement replaces the legislative financial statement presented by the Commission in conjunction with the 'REACH' proposal COM(2003)644)

Policy area(s): 02 – ENTERPRISE

Activit(y/ies): 04 – GETTING STILL MORE FROM THE INTERNAL MARKET

TITLE OF ACTION: 04 – FUTURE CHEMICALS LEGISLATION (REACH) AND THE CREATION OF A CHEMICALS AGENCY

Introduction

Consistent with the indication given by the Commission in its proposed Communication (ref …) to the European Parliament with regard to the common position of the Council on the adoption of the REACH regulation, the Annex (herewith) includes details of the revised financial implications, notably the budgetary requirements for the Agency in the years 2007/2009 during which the Agency's income will not be sufficient to cover its costs. These details will be required to enable the Commission to provide the necessary explanations to the Budgetary Authority with regard to the principal implications of the political agreement adopted unanimously by the Council, and which will shortly be approved in the form of the Council's common position.

A global overview of the additional budget needs of the new Chemicals Agency have already been brought to the attention of the Commission in the framework of the ***Statement of Estimates of the Commission for 2007*** **Document** ***V Financial Programming 2007-2013*** (SEC (2006)625/4), approved Commission on 24 May 2006 (PV (2006) 1746 point 9) as part of the financial programming for the period 2007-2013.

Decision required

The Commission's approval is sought to make the detailed figures available to the Budgetary Authority with the indication, in accordance with the financial programming document referred to above, that, taking into account projected savings in other expenditure items within Enterprise policy area, it is estimated that, in addition to the subsidy of € 15.4 m in 2007, the net requirement for the new Chemicals Agency for the years 2008 and 2009 will be of the order of € 80 m in total.

1. NAME OF THE PROPOSAL

Regulation of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency and amending Directive 1999/45/EC and Regulation (EC) {on Persistent Organic Pollutants}

2. ABM / ABB FRAMEWORK

Policy Area(s) concerned and associated Activity/Activities:

Enterprise – Internal Market for Goods and Sectoral Policies

3. BUDGET LINES

3.1 Budget lines (operational lines and related technical and administrative assistance lines (ex- BA lines)) including headings:

020301 Operation and development of the internal market, particularly in the fields of notification, certification and sectoral approximation

For the financing of actions related to the preparations for the new chemicals legislation such as the development of technical guidance documents, the development of the operational IT systems for the Agency and the initial set up of the IT infrastructure of the Agency to allow for an immediate start in Helsinki[1] upon entry into force.

2006 and 2007 budgetary comment provides for the financing of certain preparatory work in connection with the implementation of Community policy on chemical substances and with a view to setting up the future Chemicals Agency in Helsinki, including the definition and the setting up of a new IT infrastructure. This preparatory work includes in particular the continuation of the development of a computerised tool/database for the cataloguing and management of chemicals and the preparation and translation of Technical Guidance Documents.

02010401 Operation and development of the internal market, particularly in the fields of notification, certification and sectoral approximation — Expenditure on administrative management

Provides for the financing of contract agents recruited in 2006 to be trained in technical and scientific matters and also provides for the financing of initial Management Board Meetings. Such agents, when trained, are intended to be recruited by the Chemicals Agency to form the nucleus of the start-up team required to undertake the essential operational tasks of the Agency.

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[1] A decision was taken by the heads of state in December 2004 to locate the future Chemicals Agency in Helsinki, Finland (and not as foreseen in the Commission proposal in Ispra, Italy)

The 2007 proposed budgetary comment will provide for technical and scientific assistance connected with the creation and proper functioning of the future Chemicals Agency in Helsinki. Appropriations will cover the employment of external staff and their training as well as the initial meetings of the Management Board until such expenditure can be met by the Agency. In order to ensure an orderly transfer of the relevant competences and knowledge of the European Chemical Bureau (an integral part of the Commission's Joint Research Centre, JRC), to the Agency, the scientific staff training will be carried out by the JRC.

02030301 Chemicals legislation and Chemicals Agency

This new budget line is intended to cover the Agency's staff, and administrative expenditure (titles 1 and 2).

02030302 Chemicals legislation and Chemicals Agency

This new budget line is intended to cover the Agency's operating expenditure in connection with the work programme (title 3).

3.2 Duration of the action and of the financial impact:

The duration of the main phase of the action is 15 years (from 2007 to 2021).The bulk of the work envisaged for the future Chemicals Agency will concern the registration and evaluation of some 30,000 so-called "phase-in" (existing) substances. The registration of the existing substances will be finalised 11 years after entry into force. In addition, a further 4 years will be required to manage the resulting peak in work on dossier evaluations, that is, checking that the information provided by applicants conforms to the requirements.

Thereafter, the Agency will continue to carry out its functions (with a smaller staff) such as the registration of "non-phase-in" substances, updates of previous registrations, evaluations, the authorisation and restriction of substances, and providing technical and scientific guidance to the Commission, Member States and industry, notably SMEs, improving international cooperation, and capacity building in developing countries.

The indicative timetable (assuming that co-decision by Parliament and Council takes place in December 2006 at latest, that the Regulation enters into force on 1 April 2007, and that the Agency receives its budget as of 1 July 2007) is as follows:

Timing	Title	Description
January – April 2007	Preparatory period	The Commission services continue with the preparations for the setting up of the Chemicals Agency. During this period activities are financed from the internal market line and the related BA line (see above)
April – June 2007	Transition period	The Regulation will enter into force but the Agency's budget line is not yet available; therefore funding continues from the internal market line and the related BA line (see above)
July 2007 – March 2008		The proposed Regulation (Article 137 (2)) foresees that, in the case of a number of key requirements of REACH, which correspond to those for which a fully operating agency is needed, the requirements shall apply 12 months after entry into force of the Regulation. Therefore, the first 12 months after entry into force will be focused on setting up the Agency, including building up its human resources, and its constituent committees to ensure that it can be fully functioning as of April 2008. The proposed Regulation (Article 131) also foresees that in the interim the Commission may appoint personnel and conclude contracts on behalf of the Agency and thereby execute its budget until an Executive Director has been appointed (taking up duty of the Executive Director is foreseen earliest possible in November 2007).
April 2008	Agency fully operational	In accordance with Article 73 of the proposed Regulation, the Agency, by virtue of its effective administration of REACH requirements and the provision of scientific and technical advice, will be central to the achievement of the aims of the REACH system.

3.3 Budgetary characteristics:

Budget line	Type of expenditure		New	EFTA contribution	Contributions from applicant countries	Heading in financial perspective
020301	Non-comp	Diff.	NO	YES	NO	**No 1a**
02010401	Non-comp	Non-diff	NO	NO	NO	**No 1a**
02030301	Non-comp	Diff.	NO	NO (*)	NO	**No 1a**
02030302	Non-comp	Diff.	NO	NO (*)	NO	**No 1a**

(*) Is planned to be negotiated but entry into force unknown

4. SUMMARY OF RESOURCES

4.1 Financial Resources

4.1.1. Summary of commitment appropriations (CA) and payment appropriations (PA)

EUR million (to 3 decimal places)

Expenditure type	Sec-tion no.		**2007**	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**Total**
Operational expenditure										
Commitment approp. (CA)	8.1	a	15.294 + 3.180[2]	62.619	66.040	0	0	0	0	147.133
Payment approp. (PA)		b	15.294 + 3.180	62.619	66.040	0	0	0	0	147.133

[2] The first amount (€ 15.294 million) refers to the required Community contribution for the Chemicals Agency (starting July 2007) and the second amount (€ 3.180 million) refers to the funding required for additional preparatory actions for the Chemicals Agency (between January and June 2007).

Administrative expenditure within reference amount

Technical & administrative assistance (NDA)	8.2.4	c	1.735	0.300	0.300	0.300	0.300	0.300	0.300	3.535
TOTAL REFERENCE AMOUNT (these figures are not indexed for future periods (n+x))										
Commitment Appropriations	a+c		20.209	62.919	66.340	0.300	0.300	0.300	0.300	150.668
Payment Appropriations	b+c		20.209	62.919	66.340	0.300	0.300	0.300	0.300	150.668

Administrative expenditure <u>not</u> included in reference amount (these figures are not indexed for future periods (n+x))

Human resources and associated expenditure (NDA)	8.2.5	d	--	--	--	--	--	--	--	--
Administrative costs, other than human resources etc. not included in reference amount (NDA)	8.2.6	e	--	--	--	--	--	--	--	--
Total indicative financial cost of intervention (these figures are not indexed for future periods (n+x))										
TOTAL CA including cost of Human Resources	a+c+d+e		20.209	62.919	66.340	0.300	0.300	0.300	0.300	150.668
TOTAL PA including cost of Human Resources	b+c+d+e		20.209	62.919	66.340	0.300	0.300	0.300	0.300	150.668

Co-financing details

Co-financing body	***<u>Not applicable</u>***

4.1.2 Compatibility with Financial Programming

☐ Proposal is compatible with existing financial programming.

X Proposal will entail reprogramming of the relevant heading in the financial perspective.

X Proposal may require application of the provisions of the Interinstitutional Agreement3 (i.e. flexibility instrument or revision of the financial perspective).

4.1.3 Financial impact on Revenue

X Proposal has no financial implications on revenue

There is no impact on the revenue side of the Community budget. The Agency's budget foresees (i) its own revenues consisting of fees and charges for items such as registrations, applications for authorisation, production and process oriented research and design (PPORD) applications, appeal fees, fees for confidentiality claims, etc. which the Agency is authorised to collect by virtue of the tasks entrusted to it, and (ii) a balancing subsidy from the Community budget.

There will be a considerable and inevitable variation in annual fee income which is accounted for mainly from registration of substances. This is because registration deadlines are fixed at three yearly intervals in function mainly of volume of production and consequent fee income will be highest in the year of expiry of the deadlines. Consequently as regards the required EC balancing subsidy, the Agency should be allowed, in accordance with Article 185 of the Commission Financial Regulation4 to foresee, in its own financial regulation, with the Commission's prior consent, the creation of a reserve fund made up of surplus fee income. The balancing subsidy will be at its highest in the initial years i.e. before significant fee income becomes available to the Agency, namely, 2007, 2008 and 2009, as the first registration deadline is likely to occur in or around 1 April, 2010. This situation is to be contrasted with the schedule envisaged when REACH was proposed, at which stage it was estimated that, by the year 2009, the Agency would have sufficient fee income such as not to require any subsidy.

☐ Proposal has financial impact – the effect on revenue is as follows:

not applicable

[3] See points 21 and 27 of the interinstitutional agreement (OJ C 139, 14.6.2006, p.1)

[4] COM (2002) 1605 of 25 June 2002

4.2 Human Resources FTE (including officials, temporary and external staff) – see detail under point 8.2.1.

Annual requirements	2007	2008	2009	2010	2011	2012 and later
Total number of human resources	--	--	--	--	--	--

5. CHARACTERISTICS AND OBJECTIVES

5.1 Need to be met in the short or long term

The essential goals are to reduce the risks posed by chemical substances, and thereby to improve protection of health and the environment, while at the same time framing and administering the requirements in such a way as maintain industrial competitiveness and encourage innovation. These goals will be achieved by requiring appropriate data from enterprises for registering some 30,000 "existing" substances on the market, by placing the onus on producers, importers and users of substances to identify the hazards of such substances and the risk reduction measures where required, and to communicate these measures along the supply chain. Furthermore, a new instrument, namely, authorisation of use of substances of high concern, together with streamlining the existing system for introducing restrictions on other dangerous substances is an essential part of the risk reduction aims of the regulation. There are provisions also for encouraging innovation and maintaining competitiveness, as well as for making publicly available information on the risks attached to substances, with appropriate safeguards linked to commercial confidentiality.

The full background and justification for the measures proposed is given in the explanatory memorandum attached to the Commission's initial proposal (ref.: COM (2003) 644).

It should be stressed that the REACH regulation should not be seen as the simple replacement of one set of requirements by another broadly comparable system which requires an equivalent commitment of resources. REACH will bring about a fundamental change of the existing acquis on chemical substances by introducing minimum data requirements and assessment obligations for all substances and will set the bar at a higher level than at present in relation to the knowledge, awareness, and communication of hazards and risks. As such, it will require also a higher level of resource commitment by enterprises and by public authorities, including at the European level.

In the short to medium term the aim will be to ensure the efficient collection, sharing, and presentation of hazard data and implementation of risk management measures in relation to substances, to ensure that the registration requirements are properly fulfilled, to identify the substances for further evaluation (deeper investigation), and to begin to identify the priority substances for inclusion in the authorisation system, and the substances to be the subject of restrictions.

In the longer term the aim will be to increase knowledge and awareness at all levels, namely, producers, importers, industrial users, workers and consumers about the risks of substances, to encourage them to act in function of this knowledge, and to allow the authorities to adopt the necessary measures to reduce risk on the basis of comprehensive information.

From the outset it will be the aim also to encourage the development of "non-phase-in" (new) substances, especially those which are likely to pose fewer risks, to ensure that the risks from substances of very high concern are properly controlled and that these substances are eventually replaced by suitable alternative substances or technologies where these are economically and technically feasible.

5.2 Value-added of Community involvement and coherence of the proposal with other financial instruments and possible synergy

There are several elements which justify the value-added of Community involvement in this field. These are the legal basis (Article 95) for the proposal which aims to ensure a level playing field within the internal market while, at the same time, ensuring a high level of protection of health and the environment, the need for full harmonisation of the requirements, and the fact that the new proposal replaces and extends in a coherent way a large number of individual existing legislative measures, for example, in relation to registration of "new" substances, classification and labelling of substances and of preparations, the restriction on marketing and use of certain substances, and the legislation on the assessment of "priority" substances.

The proposal also meets the requirements of subsidiarity and proportionality, especially insofar as the actors concerned are given added responsibility for their substances; besides, the measures do not go beyond what is necessary to achieve the health and environment aims of the regulation, and introduce cost-efficient mechanisms, for example, in relation to sharing of information in order to minimise the costs for enterprises.

Fuller details of these justifications are set out in the explanatory memorandum attached to the Commission's initial proposal. (Ref: COM (2003)644).

5.3 Objectives, expected results and related indicators of the proposal in the context of the ABM framework

Objectives

The objectives of the REACH proposal are to ensure a high level of protection of health and the environment as well as the free circulation of substances on the internal market, while enhancing competitiveness and innovation.

To achieve these objectives it is necessary that the hazards and risks of substances are fully known to producers and importers of substances, that the measures to manage the risks are properly communicated along the supply chain, and that the public authorities have available the necessary information to enable them to take timely and well founded decisions related to the exercise of their responsibilities, particularly under the evaluation, authorisation and restriction of substances of high concern.

To ensure the efficient implementation of the new requirements it is necessary to establish a European Chemicals Agency which will receive and manage data submitted by industry, for example, for the purpose of registration, evaluation, restrictions and authorisation of substances, and will be the focal point for providing scientific advice and assistance to the Commission, to Member State authorities, to enterprises, especially SMEs, and for making available relevant information to the public.

The free circulation of substances on the internal market and enhancing competitiveness and innovation will be supported by having a coherent approach to the treatment of dossiers submitted by industry, by introducing special incentives in the area of research and development, and by encouraging the development of 'new' substances, so as to enable Europe to compete better with its international competitors, and bring about the greater availability of substances with lower risks.

Expected results

Due to a lack of comprehensive data, a reliable quantitative assessment of the impact of chemical substances on the environment and on human health is not possible. Indeed, the very purpose of REACH is to make available, and, if necessary, to newly generate much of the missing data. Accordingly, the benefits will occur on a gradual basis as knowledge is increased, the actors concerned become more aware of the need and introduce themselves the measures to reduce the risks, and risk reduction measures are decided and implemented by the Commission. The benefits will be measurable only over a longer time frame.

Nevertheless, results of the high number of impact assessments carried out on the proposal both by the Commission services and by others are consistent in pointing out that the proposed regulation is likely to:

– contribute significantly to improved health for the citizens of the EU generally and bring about greater protection of the environment;

– bring added benefits in particular for worker safety and

– improve the conditions for innovation by making it easier and less costly to develop new and safer substances; also by focusing on priorities and providing maximum opportunity to limit costs, for example, by information sharing and development of non-animal tests, REACH will maintain the competitiveness of industry.

Indicators

It is planned to keep under review the principal impacts resulting from the new policy (see impact assessment studies Section 6.2) in order to ensure that the new measures will result in a balanced outcome, as required by the sustainable development strategy which is a key consideration in the approach proposed.

In the first instance a base-line study is being undertaken for the purpose of measuring the incidences and types of ill-health induced by chemicals, and of environmental damage caused by chemicals. This should permit the identification of a methodology for measuring these aspects at pre-determined intervals as the beneficial effects of REACH are experienced over time.

As regards performance indicators, as regards health and environment, in the initial phases these will be designed to measure activity which is linked to further investigating and acting on risks from substances. It is only later that effects on health and environment can be properly monitored.

In addition, performance indicators identified to date are as follows:

Objective	Indicators for the policy
Protection of human health and the environment	• Agency's report on evaluations of testing proposals conducted over the previous year[5] • Member States' reports on enforcement activities[6] • Number of dangerous substances, in particular PBTs[7], vPvBs[8] and CMRs[9] identified
Harmonisation of evaluation	• Number of draft evaluation decisions referred to the Member State Committee in the Agency
Timely introduction of Community risk reduction measures	• Number of authorisation/restriction cases dealt with • Time from receiving a complete dossier to appropriate risk reduction measures being agreed
Maintenance and enhancement of the competitiveness of the EU chemical industry	• Number of companies active in the chemicals sector (including share of SMEs) • Development of exports/imports of the European chemicals industry • GDP contribution of the chemicals sector and value added • Level of employment in the chemicals sector
Promotion of innovation	• Number of new substances registered • Number of PPORDs[10] applied for
Prevent fragmentation of the internal market	• Number of infringement cases under Article 95 of the Treaty
Increased transparency	• Number of searches on the databases • Numbers of request for information for non-confidential data
Promotion of non-animal tests	• Availability of valid QSARs[11] • Number of in-vitro test methods developed • Number of vertebrate test animals used in relation to number of tests performed
Cost-effectiveness of	• Number of registration dossiers received from

5 Article 51 of the Regulation stipulates 'By 28 February of each year, the Agency shall publish on its website a report on the progress made over the previous calendar year towards discharging the obligations incumbent upon it in relation to evaluation. …..'.

6 According to Article 124 of the regulation 'the report shall, in relation to enforcement, include the results of the official inspections, the monitoring carried out, the penalties provided for and other measures taken'.

7 Persistent, bioaccumulative and toxic substances

8 very persistent and very bioaccumulative substances

9 Carcinogenic, mutagenic and reprotoxic substances

10 Product and Process Oriented Development

11 Qualitative structure activity relationships (alternative testing method)

centralised registration process	industry • Number of registrations refused (completeness check)
Accuracy of Agency decision making	• Number of appeals received • Number of appeals upheld

5.4 Method of Implementation (indicative)

Show below the method(s) chosen for the implementation of the action.

– Centralised Management

X Directly by the Commission

Indirectly by delegation to:

– Executive Agencies

X Bodies set up by the Communities as referred to in Art. 185 of the Financial Regulation

– National public-sector bodies/bodies with public-service mission

– Shared or decentralised management

– With Member states

– With Third countries

– Joint management with international organisations (please specify)

Relevant comments

The Agency will play a central role in receiving and managing data from enterprises which register their substances, in evaluating the dossiers presented, in establishing a rolling plan for the evaluation (deeper investigation) of substances under suspicion, in managing applications for authorisation of substances of very high concern, in proposals for restrictions of dangerous substances, proposals for harmonised classification and labelling, and in providing technical and scientific advice to enterprises notably to SMEs and to the Commission. Based on the opinions received from the Agency, the Commission will prepare decisions for risk reduction measures to be adopted through the Comitology procedure.

The Agency's powers and responsibilities are specified in the regulation. Its decisions are, for the most part subject to appeal, a situation which requires the establishment within the Agency of structures for dealing with appeals. The structures of the Agency will comprise a Management Board, composed of representatives from all Member States, together with 6 nominees of the Commission, 3 of whom will represent stakeholders. There will also be 4 individual constituent bodies within the Agency, namely, committees dealing with risk assessment, socio-economic analysis and divergences of opinion among Member States on draft decisions, together with forum for the exchange of information. This is in addition to a secretariat which, working under the authority of the Executive Director, will provide technical, scientific and administrative support to the committees. The Management Board will have typical functions associated with regulatory agencies, in particular, the power to appoint the Executive Director and the Accounting Officer, to approve the work programme, the draft budget, to give an opinion on the annual accounts, etc.

As regards the personnel of the Agency, these will comprise a considerable proportion of scientific/technical staff to deal with the complex technical work of the Agency, expert staff to deal with IT matters as an effective IT system is central to the smooth operation of the Agency, and administrative support staff.

As substantial responsibilities will fall on the Agency from 12 months after entry into force of the regulation, there will have to be a rapid build up of the Agency's staff, starting from about 100 in 2007, 250 by end of 2008, and between 400-450 staff as of 2010.

Full details of projected staffing levels are given in Annex III.

6. MONITORING AND EVALUATION

6.1 Monitoring system

In order to evaluate the progress of implementation and effects of the new policy, the indicators as set out in 5.3 will be gathered and monitored at regular intervals. For the most part, this will be done as part of the normal activity of the Agency on an annual basis.

As indicated, REACH is founded in the EU wider sustainable development strategy. As such, its central aim is to achieve sustainable development by ensuring both a high level of protection of human health and the environment and competitiveness of industry, within the framework of the Single Market. Accordingly, the indicators presented will have to address both the health and environment and the economic pillars of the sustainable development strategy.

A key question aspect is to see how REACH will ensure the smooth operation of the internal market; in this case the primary focus is on a specific economic sector, namely, the chemicals sector.

One indicator to measure the degree of effective harmonisation in chemicals is the number of national measures introduced or notified in this area, and the number of internal conflicts which, under the impact of REACH, should normally be expected to reduce. This will be considered during the yearly monitoring process and the evaluation of REACH.

The other principal indicators will enable an assessment to be made of the extent to which further investigation is being undertaken into the hazards and risks of substances, and how far and how fast the system is responding to the need to address situations where risk reduction measures are needed. Other classic indicators of economic and social impacts on the chemicals industry, for example, output, exports, employment, are also foreseen.

Apart from the specific indicators mentioned, the REACH regulation will be the subject of a high level of monitoring and review at several levels. These review requirements are set out in Article 114 (Reporting):

1. **Every five years, Member States shall submit** to the Commission **a report** on the operation of this Regulation in their respective territories, including sections on evaluation and enforcement ….

The first report shall be submitted three years after the entry into force of this Regulation.

2. **Every five years**, the **Agency shall submit to the Commission a report** on the operation of this Regulation. The Agency shall include in its report information on the joint submission of information in accordance with Article 10 and an overview of the explanations given for submitting information separately.

However, the first report shall be submitted four years after entry into force of this Regulation.

3. **Every five years**, the **Commission shall publish a general report** on the experience acquired with the operation of this Regulation, including the information referred to in paragraphs 1 and 2.

6.2 Evaluation

6.2.1 Ex-ante evaluation

The Extended Impact Assessment SEC (2003)1171/3 which accompanied the Commission's proposal of October 2003 reports total direct costs of the REACH requirements for companies at 2.3 billion Euro. The largest share of these costs is accounted for by registration and testing costs. The reported total costs are in the range of € 2.8 to € 5.3 billion; the cost range is related to the degree of substitution of chemicals required of downstream users where for economic reasons substances may be withdrawn from the market and have to be replaced by more costly substitutes; in this case the assumed REACH induced withdrawal rate is 1-2% of the substances to be registered.

All costs figures are over the first 15 years after REACH has entered into force. Apart from quantified costs, it is to be noted also that the qualitative analysis of innovation and business benefits from REACH given in the assessment shows that the effects are positive. The report notes that the benefits on human health and the environment are difficult to appraise but are expected to be substantial. An illustrative quantitative calculation identifies such benefits at €50 billion over 30 years.

The background documents, together with the Extended Impact Assessment available on the Europe webpage http://europa.eu.int/comm/enterprise/reach/eia_en.htm, document the methodologies used for the various parts of the appraisal exercise.

The REACH proposal has been the subject of a very large number of impact assessments. These have varied in quality and the absence of independent validation of the results has tended to be a problem for the credibility of some such exercises.

Despite such limitations, the initial impact assessment by the Commission services has not been called into question in a fundamental way. For example, an overview study of about 30 REACH Impact Assessment studies, which was commissioned by the Netherlands Presidency in 2004, corroborated the main conclusions of the Commission's Extended Impact Assessment studies. Most of the studies reviewed found direct costs estimates in or around the same magnitude as the Commission's Extended Impact Assessment, and concluded also that the health and environmental benefits are likely to be several times higher than the costs, though acknowledging that these are very difficult to quantify.

Apart from the aforementioned studies, a special exercise has been carried out in conjunction with industry and in the presence of other stakeholders to probe more deeply the economic effects within enterprises of the application of the main REACH mechanisms. This initiative was taken following a conference on the REACH proposal and Impact Assessment in November 2003 at which industry stakeholders expressed serious concerns about the impact of REACH on enterprises especially as regards lower volume substances and SMEs and the consequences of the added costs on their competitiveness. As a result additional work was undertaken with industry and other stakeholders in order to examine the issues raised. This was done through business case studies which provided the opportunity to examine how, in real-life business situations, the mechanisms of REACH would impact. The conclusions from the work is that there was limited evidence of withdrawal of substances of greatest technical importance; if substantial withdrawal of substances occur, the costs, for example, as a result of replacing substances and of reformulation and re-engineering, would be significant for downstream companies; SMEs could be particularly affected, and the impacts on innovation were uncertain, especially in the short term. Some business benefits were also recognised. Details can be seen at http://europa.eu.int/comm/enterprise/reach/eia_en.htm.

http://europa.eu.int/comm/enterprise/reach/docs/reach/note_further_ia.pdf

On the basis of these, and other studies with similar outcomes, the Competitiveness Council of 6 June 2005, having considered all the elements, concluded that it had "sufficient knowledge available to allow the negotiations to continue on the basis of the Commission's proposal". The impact assessment results and the conclusions drawn from these exercises have been a valuable input to the deliberations of Parliament and of the Council for the purpose of framing the amendments to the Commission's proposal, as adopted at the First Reading of Parliament (November 2005) and the Political Agreement of the Council (December 2005).

6.2.2 Measures taken following an intermediate/ex-post evaluation (lessons learned from similar experiences in the past)

The entire REACH proposal is founded on a comprehensive analysis of the deficiencies of the existing rules on chemical substances. Among the problems identified are the slowness with which the risk assessment of priority substances has been carried out to date and of the slowness procedures for applying Community risk reduction measures. Accordingly, the key changes from the existing regime concern the reversal of the burden of proof away from public authorities and, in consequence, the responsibility placed on companies to identify the hazards and necessary risk reduction measures in the case of 30.000 substances, and to communicate these effectively throughout the supply chain.

The need also in the context of an enlarged EU, to ensure effective application of the measures which for the present are contained in some 40 individual legal provisions, mainly Directives and Decisions, led to the proposal for a regulation, which would be directly applicable, and would provide the opportunity for the simplification of the relevant requirements.

6.2.3 Terms and frequency of future evaluation

The main indicators identified in Section 5.3 will be collected by the Agency and the Commission, as far as possible on an annual basis. Results will be published in the annual report of the Agency. As indicated in Section 6.1 a general report will be prepared by the Agency and submitted to the Commission, which in turn will present its review report, every five years.

7. ANTI-FRAUD MEASURES

In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1037/1999 shall apply without restrictions to this Agency.

The Agency shall accede to the Interinstitutional Agreement of May 25, 1999 concerning internal investigations by Olaf and shall issue, without delay, the appropriate provisions applicable to its entire staff.

The decisions concerning funding and the implementing agreements and instruments resulting from them shall explicitly stipulate that the Court of Auditors and Olaf may carry out, if necessary, on-the-spot checks of the recipients of the Agency's funding and the agents responsible for allocating it.

8. DETAILS OF RESOURCES

8.1 Objectives of the proposal in terms of their financial cost

Commitment appropriations in EUR million (to 3 decimal places)

(Headings of Objectives, actions and outputs should be provided)	**Type of out-put**	**Av. cost**	**Year n**		**Year n+1**		**Year n+2**		**Year n+3**		**Year n+4**		**Year n+5 and later**		**TOTAL**	
			No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost	No. outputs	Total cost
OPERATIONAL OBJECTIVE No.1	REACH is an integrated project founded on the need to respect the individual pillars of the EU sustainable development strategy. As such it aims to improve health and the environment, to maintain employment and improve worker protection, and also to maintain industrial competitiveness and encourage innovation. The resources to be devoted to this action have to be considered as allocated to the achievement of the overall sustainable development goal and as such can not be broken down between the constituent (health and environment, social, and economic) aims.															
TOTAL COST	**Please refer to Annex I for a detailed breakdown of the Agency's costs and to Annex II for the main underlying assumptions and the main reasons for the changes in costs compared to the initial legislative financial statement.**															

8.2 Administrative Expenditure

*8.2.1 Number and type of human resources**

Types of post		Staff to be assigned to management of the action using existing and/or additional resources (**number of posts/FTEs**)					
Years		**2007**	**2008**	**2009**	**2010**	**2011**	**2012 and later**
Officials or temporary staff (XX 01 01)	A*/AD	--	--	--	--	--	--
	B*, C*/AST	--	--	--	--	--	--
Staff financed by art. XX 01 02 (END, contract staff)		--	--	--	--	--	--
Other staff financed by art. XX 01 04/05		--	--	--	--	--	--
TOTAL		**--**	**--**	**--**	**--**	**--**	**--**

8.2.2 Description of tasks deriving from the action

Not applicable

8.2.3 Sources of human resources (statutory)

(When more than one source is stated, please indicate the number of posts originating from each of the sources)

☐ Posts currently allocated to the management of the programme to be replaced

☐ Posts pre-allocated within the APS/PDB exercise for year 2007

☐ Posts to be requested in the next APS/PDB procedure (2008)

☐ Posts to be redeployed using existing resources within the managing service (internal redeployment)

☐ Posts required for year 2007 although not foreseen in the APS/PDB exercise of the year in question

8.2.4 Other Administrative expenditure included in reference amount (XX 01 04/05 – Expenditure on administrative management)

EUR million (to 3 decimal places)*

Budget line (number and heading) 02.010401	2007	2008	2009	2010	2011	2012	2013	Total
1 Technical and administrative assistance (including related staff costs)								
Executive agencies	--	--	--	--	--	--	--	--
Other technical and administrative assistance	--	--	--	--	--	--	--	--
- *intra muros*	1.600	--	--	--	--	--	--	1.600
- *extra muros*	0.135	0.300	0.300	0.300	0.300	0.300	0.300	1.935
Total Technical and administrative assistance	1.735	0.300	0.300	0.300	0.300	0.300	0.300	3.535

* *These figures are not indexed for future periods (n+x)*

Intra muros:

These are costs related to contract agents/ENDs hired by DG ENTR in 2006 for the purpose of training them in technical and scientific matters so that they can be transferred (after having undergone the appropriate recruiting procedures) to the Chemicals Agency to form the operational nucleus.

Extra muros:

2007: These costs relate to the reimbursement costs of initial Board meetings planned between April and June 2006 (at which point in time it is expected that the Agency's budget line is not yet available).

2008 and thereafter: These are the estimated costs for scientific/technical advise the Commission may seek with regard to the opinions based on which the Commission has to take decisions by way of Comitology procedure.

8.2.5 Financial cost of human resources and associated costs not included in the reference amount

EUR million (to 3 decimal places)

Type of human resources	2007	2008	2009	2010	2011	2012	2013
Officials and temporary staff (02 01 01 and 07 01 01)	--	--	--	--	--	--	--
Staff financed by Art 02 01 02 and 07 01 02 (END and contract staff)	--	--	--	--	--	--	--
Total cost of Human Resources and associated costs (NOT in reference amount)	--	--	--	--	--	--	--

Calculation– ***Officials and Temporary agents***

8.2.6 Other administrative expenditure not included in reference amount

EUR million (to 3 decimal places)

	2007	2008	2009	2010	2011	2012	2013
XX 01 02 11 01 Missions	--	--	--	--	--	--	--
XX 01 02 11 02 Meetings & Conferences	--	--	--	--	--	--	--
XX 01 02 11 03 Committees[12]	--	--	--	--	--	--	--
XX 01 02 11 04 Studies & consultations	--	--	--	--	--	--	--
XX 01 02 11 05 IT systems	--	--	--	--	--	--	--
2 Total Other Management Expenditure (XX 01 02 11)							
	--	--	--	--	--	--	--
3 Other expenditure of an administrative nature (specify including reference to budget line							
	--	--	--	--	--	--	--
Total Administrative expenditure, other than human resources and associated costs (NOT included in reference amount)							
	--	--	--	--	--	--	--

Calculation - ***Other administrative expenditure <u>not</u> included in reference amount***

[12] REACH Comitology committee

Draft Budget for European Chemicals Agency

In '000 Euros		2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
1	STAFF IN ACTIVE EMPLOYMENT	**9.101**	**33.329**	**43.395**	**53.397**	**54.503**	**57.314**	**56.640**	**48.579**	**47.471**	**40.186**	**42.120**	**62.396**	**52.910**	**52.155**	**51.695**
		60%	**50%**	**59%**	**63%**	**61%**	**61%**	**63%**	**59%**	**59%**	**51%**	**55%**	**64%**	**61%**	**60%**	**61%**
	STAFF IN ACTIVE EMPLOYMENT	5.934	26.454	37.687	47.311	49.362	51.948	51.661	43.966	43.172	36.255	38.025	54.604	47.974	47.497	47.084
	MISCELANEOUS EXPENDITURE ON STAFF RECRUITMENT AND TRANSFER	1.151	4.492	3.572	3.476	2.422	2.531	2.167	2.148	1.875	1.844	1.921	4.811	2.280	2.026	2.007
	MISSIONS AND DUTY TRAVEL EXPENSES	1.944	1.367	711	874	912	952	944	824	810	694	724	1.002	890	882	872
	SOCIOMEDICAL INFRASTRUCTURE	48	967	1.375	1.686	1.758	1.834	1.819	1.591	1.564	1.344	1.401	1.929	1.716	1.701	1.682
	EXCHANGES OF CIVIL SERVANTS AND EXPERTS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
	ENTERTAINMENT AND REPRESENTATION EXPENSES	25	50	50	50	50	50	50	50	50	50	50	50	50	50	50
2	BUILDING, EQUIPMENT AND MISCELLANEOUS OPERATING EXPENDITURE	**2.581**	**13.077**	**9.497**	**9.722**	**10.564**	**12.187**	**10.388**	**9.592**	**9.526**	**10.548**	**9.523**	**10.822**	**9.820**	**11.441**	**9.904**
		17%	**20%**	**13%**	**11%**	**12%**	**13%**	**11%**	**12%**	**12%**	**13%**	**12%**	**7%**	**7%**	**9%**	**7%**
	RENTAL OF BUILDINGS AND ASSOCIATED COSTS	935	7.327	5.367	6.083	6.638	6.813	6.778	6.253	6.192	5.684	5.815	7.032	6.542	6.507	6.463

	INFORMATION AND COMMUNICATION TECHNOLOGY	928	4.135	2.395	2.340	2.603	4.091	2.331	2.129	2.132	3.680	2.116	2.478	2.030	3.691	2.478
	MOVABLE PROPERTY AND ASSOCIATED COSTS	401	1.030	997	520	535	485	482	445	440	451	851	501	465	463	185
	CURRENT ADMINISTRATIVE EXPENDITURE	97	264	418	459	468	478	476	446	443	414	421	491	463	461	458
	POSTAL CHARGES AND TELECOMMUNICATIONS	195	280	280	280	280	280	280	280	280	280	280	280	280	280	280
	EXPENDITURE ON FORMAL AND OTHER MEETINGS NOT RELATED TO THE WORK PROGRAMME OF THE AGENCY	25	40	40	40	40	40	40	40	40	40	40	40	40	40	40
3	OPERATING EXPENDITURE	**3.612**	**20.018**	**20.919**	**22.268**	**24.992**	**23.782**	**23.554**	**23.489**	**24.008**	**28.746**	**24.591**	**23.574**	**23.542**	**23.540**	**23.589**
		23%	**30%**	**28%**	**26%**	**28%**	**25%**	**26%**	**29%**	**30%**	**36%**	**32%**	**26%**	**29%**	**28%**	**29%**
	OPERATING EXPENDITURE	1.594	10.239	10.239	10.239	10.239	10.239	10.239	10.239	10.239	10.239	10.239	10.239	10.239	10.239	10.239
	DEVELOPMENT OF DATABASES AND SOFTWARE TOOLS RELATED TO THE OPERATION OF REACH	1.269	1.468	1.484	1.414	1.437	1.454	1.467	1.476	1.483	1.489	1.493	1.496	1.498	1.500	1.501
	ACTIVITIES OF THE FORUM	-	562	562	562	562	562	562	562	562	562	562	562	562	562	562
	ACTIVITIES OF THE MEMBER STATE COMMITTEE	-	305	305	305	305	305	305	305	305	305	305	305	305	305	305

ACTIVITIES OF THE RSISK ASSESSMENT AND THE SOCIO ECONOMIC ANALYSIS COMMITTEE	-	3.789	5.974	7.224	8.499	8.499	8.499	8.499	8.499	8.499	8.499	8.489	8.499	8.499	8.049
EVALUATION ACTIVITIES	-	-	133	267	267	267	267	267	267	267	267	267	267	267	267
APPEAL BODY	-	1.809	438	187	1.096	343	103	103	622	4.916	1.242	82	97	97	97
INFORMATION AND PUBLICATIONS	50	120	180	180	180	180	180	180	180	180	180	180	180	180	180
HELPDESK SERVICES	500	800	800	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000	1.000
STUDIES AND CONSULTANTS	-	100	200	200	700	200	200	200	200	700	200	200	200	200	700
MISSION EXPENSES LINKED TO THE WORK PROGRAMME	199	427	305	391	409	434	433	359	353	290	306	456	396	392	390
TECHNICAL TRAINING OF STAFF AND STAKEHOLDERS	-	400	300	300	300	300	300	300	300	300	300	300	300	300	300
TOTAL BUDGET	**15.294**	**66.425**	**73.811**	**85.386**	**90.060**	**93.283**	**90.582**	**81.660**	**81.006**	**79.480**	**76.234**	**96.793**	**86.272**	**87.136**	**85.188**
EXPECTED FEES	**-**	**3.806**	**7.771**	**278.322**	**27.391**	**35.659**	**53.794**	**33.267**	**33.532**	**36.026**	**36.835**	**59.826**	**33.264**	**33.264**	**33.264**
RESERVE	**-**	**-**	**-**	**192.936**	**130.267**	**72.643**	**35.855**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**
REQUIRED COMMUNITY CONTRIBUTION	**15.294**	**62.619**	**66.040**	**-**	**-**	**-**	**-**	**12.537**	**47.473**	**43.454**	**39.400**	**36.967**	**53.007**	**53.872**	**51.924**

For comparison purposes: extract from the Financial statement included in the initial Commission proposal on REACH – reference COM (2003) 644*

TOTAL BUDGET	11.964	16.254	31.301	31.963	37.299	35.758	34.406	34.722	34.755	34.907	56.053
EXPECTED FEES	267	1.192	91.617	5.414	7.922	81.945	6.778	7.730	6.570	15.026	60.665
RESERVE	-	-	-	60.316	33.768	4.390	50.577	22.949	-	-	-
REQUIRED COMMUNITY CONTRIBUTION	11.697	15.062	-	-	-	-	-	4.042	28.185	19.881	-

* At the time of the Commission proposal it was still expected that REACH would enter into force in 2006. It was furthermore expected that the Agency would be largely self-financing from 2008 onwards.

ANNEX II
Applied methodology and main underlying assumptions for the financial model of the Chemicals Agency
and
reasons for change compared to the legislative financial statement published with the Commission proposal
Applied methodology and main underlying assumptions:

Computation of staff costs

Applied average staff costs by grade per annum

AD staff (all)	110.675,6 €
AST 5-11 (former B staff)	81.116,6 €
AST 4-11 (former C staff)	56.447,4 €

Due to the fact that the European Chemicals Bureau (ECB) in Ispra has a major role in operating current chemicals legislation, significant experience exists with regard to how long certain tasks take and what kind of qualifications are needed in order to carry them out (differentiation between different categories of staff).

Based on this experience, a staff model has been developed for the operation of REACH. The output of this staff model is how many staff (by grade) are required in a given year to fulfil the dossier-related tasks of the Agency (operational tasks of the REACH legislation). To these staff numbers additional resource requirements have been added for the management and training of these resources.

In addition, the requirements for operational (non-dossier driven tasks), e.g. for international relations, for external communication, helpdesk services, etc. have been analysed. And, in a last step the administrative functions have been examined; based on experiences of other agencies, additional resources have been added in areas such Office of the Executive Director, the Legal Department, Audit and Internal Control, Human Resources (HR), Finance, Information Technology (IT) Building Management,. For total staff required please see Annex III.

All the resources computed have been multiplied by the average annual cost by grade and that has led to the total staff costs. In addition, the weighting factor for Helsinki (119.4% as of Nov. 2005 – cost of living adjustment applicable to all staff) has been applied.

Other costs of staff in active employment have been computed based on the applicable rates of the current staff regulation, e.g. for the reimbursement of costs related to recruiting and moving when taking up duty.

Computation of building, equipment and miscellaneous operating expenditure:

It has been assumed that number of staff is the major cost driver in this area. e.g. for the rental expenses the number of staff has been multiplied by the standard average space in Finland (27 sqm gross) per member of staff and this has been multiplied with the average annual cost per sqm (€ 270) as provided by the Finnish authorities. In addition, the requirement for extra meeting space due to the size of the committees has been accounted for.

Also IT costs, expenditure for furniture and other administrative expenditure have been computed based on the number of required staff multiplied by average cost figures per person (comparable data have been obtained mostly from other agencies).

Operating expenditure:

Major cost items in this area are general operating expenditures and all expenditure related to the different Committees of the Agency.

The major cost driver for the general operating expenditure is translation costs in relation to the work programme of the Agency. These costs will be substantial since a lot of information is to be made available on the public dissemination website of the Agency.

The expenditure for the different Committees of the Agency includes reimbursement costs for Committee Members (travel, hotel, daily allowances according to currently applicable Commission rates), rapporteur fees, and other meeting expenditure such as catering costs.

[Computation of expected fee income: (provisional)

In the legislative financial statement published with the Commission proposal, it was assumed that the Agency would have a very simple fee structure (registration fees for below and above 100t - € 400 and € 8.000 respectively). In addition, it was assumed that authorisations would cost € 50.000.

The political agreement has introduced a larger number of individual fee items and also important reductions and waivers for specific cases such as SMEs and consortia which are thereby encouraged. In addition, the fee setting will no longer be subject to a decision of the Board of Management but will have to be established by a separate Fee Regulation (Commission Regulation). In that context it will be necessary to establish the fee structure, in particular the base fee payable at each registration volume, the reduction to be applied to registrants forming parts of consortia, and the reduction to be envisaged for SMEs as required by the regulation. **The rates of fees and the structure outlined in the following estimates represent only one hypothesis and are therefore provisional and without prejudice to the Commission's decision in this matter.**

For the purpose of the fee calculation it has been assumed that:

- Fees will be staggered - 4 different categories (1-10 t, >10 t – 100 t, > 100 t – 1000 t, and above 1000t)
- A reduction of 1/3 of the respective registration fee will be granted for consortium participants
- A reduction of 25% will be granted to SMEs
- PPORD applications cost € 500, PPORD renewals cost € 250
- Authorisation applications cost € 58.000
- The appeal fee amounts to € 1.500

Tonnage category	Full base fee	Consortium participants	SMEs	SMEs participating in a consortium
1 – 10 t	1.200	804	900	504
> 10 t – 100 t	3.257	2.182	2.443	1.368
> 100 t – 1000 t	8.842	5.924	6.631	3.714
> 1000 t	24.000	16.080	18.000	10.080

Reasons for change compared to the legislative financial statement published with the Commission proposal

There are two major reasons for the increased costs of the Agency, namely financial implications of the political agreement adopted unanimously by the Council on 13 December 2006 and the decision of Heads of State in December 2004 to locate the Agency in Helsinki. The main thrust of key amendments adopted in Parliament's First Reading, for example, strengthening the role of the Agency in evaluation, supporting SMEs, go in a similar direction to that of the Council.

Major cost drivers related to the Council agreement:

Change in distribution of tasks between Member States Competent Authorities and the Agency: A significant workload, and corresponding cost, has been transferred from Member State Competent Authorities to the Agency; in addition, costs have been increased through a series of new requirements, the most significant being dossier evaluations. As a consequence staff forecasts have almost doubled and it is now necessary to maintain an Agency of considerable size for at least 15 years (rather than 11 years) in order to process the bulk of the evaluation work. While it might be possible to (partially) outsource some tasks (e.g. to Member State Competent Authorities), this now requires a financial compensation that is estimated to be equivalent to the in-house cost.

Addition of helpdesk function: The Agency is now required to provide a helpdesk function to industry especially to SMEs directly for certain aspects of REACH as soon as the essential obligations are in force. In addition, the linguistic regime to be applied has direct and significant consequences on the staffing needs of the Agency. Some helpdesk functions must be provided from entry into force onwards.

Changes in deadlines: The deadline for pre-registration of substances has been brought forward. Instead of having two deadlines on a phased basis, all pre-registrations (expected to be up to 150.000) now have to be completed between 12 and 18 months after entry into force. As industry is now obliged to submit dossiers in consortia whenever possible, the pre-registration is the most powerful tool for enterprises to recognise other enterprises producing or importing the same substance and to thereby establish consortia. This single pre-registration will also help industry to identify which enterprise has which data, and to exchange such data. Therefore, the workload for the Agency regarding the pre-registration has been increased and will occur soon after the Agency has to take on substantive operational responsibilities (EIF + 12 months = April 2008 to September 2008). Because of this early deadline, a increase of agency staff is required to be able to cope with the expected increase of the workload, which not only relates to the pre-registration process as such, but also to the follow-up.

Changes in the powers of the Agency: The powers of the Agency have been considerably strengthened and as a consequence the Agency will take a larger number of decisions directly, against which industry may appeal. Consequently, the estimated number of appeals to be treated by the Appeal Body of the Agency has been increased. This in turn increases the required size of the appeal body and the related costs. As appeals may occur early on, the Appeal Body and its necessary support structure has to be in place not later than 12 months after EIF. As a significant number of appeals is expected to result from the huge number of pre-registrations and disputes during data sharing, adequate human resources are needed for the Appeal Body.

Increased size of the bodies of the Agency: In its original proposal the Commission had limited the size of the bodies of the Agency in line with the communication from the Commission regarding 'The operating framework for the European Regulatory Agencies' (COM(2002)718 final). The current text of the political agreement foresees that Member States shall be represented equally on the Management Board and its Committees. This has significantly increased the size of these bodies; as a consequence, related costs such as travel reimbursements, workload related to the organisation of meetings, size of meeting facilities required, etc. have gone up substantially.

Major cost drivers related to the change of location:

Availability of suitable staff: The original Commission proposal identified Ispra[13] as the location of the European Chemicals Agency. The main reason for this was the location of the European Chemicals Bureau (ECB), which operates part of the existing Chemicals legislation. The necessary knowledge transfer between the ECB in Ispra to the European Chemicals Agency is more complex now that it is placed in Helsinki, as suitable scientific staff from the ECB may not move to Helsinki. The same holds true for administrative staff, which could have been recruited more easily from existing JRC staff in Ispra. As a consequence, the whole approach towards staff planning has had to be adapted. The recruitment of contract agents for scientific/technical tasks in 2006 to be trained by ECB staff for future tasks in the Agency, and the secondment of officials to start-up the administrative and infrastructure tasks in year 1 of the Agency, had not been foreseen previously but are now essential to enable the Commission to meet its responsibilities in the political agreement to provide the necessary support towards the setting up of the Agency; in practice this means to have the Agency operational within 12 months after entry into force.

Application of a correction coefficient: In the case of Helsinki a correction coefficient for the cost of living adjustment of 119.4% (status November 2005) is applicable, whereby for Ispra this coefficient is slightly below 100%. This factor, together with the increased staff numbers, has increased the overall staff costs substantially.

Build up of infrastructure from day one: It had been assumed that setting up the Chemicals Agency in Ispra would provide the opportunity to avail (at least initially) of existing infrastructure and resources of the Joint Research Centre in Ispra (e.g for IT structure, data centre, etc.). Helsinki as a location now corresponds much more to a 'green field' situation in which all infrastructure has to be set up from day one and no synergies are possible with existing Institutions. This has significantly increased the start up costs for the Agency and also brought increased costs for the preparatory actions required prior to entry into force of REACH.

[13] It was planned to locate the European Chemicals Agency on the premises of the Joint Research Centre in Ispra

The total budget difference between the legislative financial statement presented with the Commission proposal and this revised financial statement amounts to € 829 million. While the original budget for the 11-year period was estimated at € 359 million the revised budget for the 15-year period now amounts to € 1.189 million. The budget comparison only includes the years during which the Agency will carry out the main task of registration all phase-in substances.

Thereafter, the Agency will continue to carry out its functions (with a smaller staff) such as the registration of "non-phase-in" substances, updates of previous registrations, evaluations, the authorisation and restriction of substances, and providing technical and scientific guidance to the Commission, Member States and industry, notably SMEs, improving international cooperation, and capacity building in developing countries.

Below, please find a direct comparison between the budget figures published in the legislative financial statement at the time of the Commission proposal in 2003 and the figures contained in this revised legislative financial statement:

Total Cost Comparison
(All figures in Euro '000)

	Initial forecast – COM (2003)	in %	**Updated forecast - May 2006**	in %	**Difference**	in %
Staff costs (salary, pensions, insurances)	191.002	53%	535.015	45%	344.013	41%
Total costs directly related to change of location	12.025	3%	173.756	15%	161.732	19%
Weighting factor applied for cost of living adjustments	--		*72.713*		*72.713*	
Rent, utility and building expenses, also including technical installations and office furniture	*12.025*		*96.408*		*84.384*	
Provisions for the support of canteen services	--		*4.635*		*4.635*	
Costs driven by number of staff (such as recruitment, training, medical services, interim services, communication services)	30.888	9%	110.379	9%	79.491	10%
Translation costs	27.500	8%	143.240	12%	115.740	14%
Costs for the reimbursement of Committee and Board members, for rapporteur fees and meetings in general (including travel, daily subsistence, hotel, venue and catering costs)	63.430	18%	125.568	11%	62.138	8%
IT hard-and software costs including costs related to the maintenance and running of REACH IT	5.976	2%	61.489	5%	55.513	7%
Costs for the reimbursement of the Appeal Body Members	2.200	1%	11.232	1%	9.032	1%
Other administrative costs – not staff driven (such as library expenditure, publication and consultancy costs)	26.360	6%	28.106	2%	1.745	0%
GRAND TOTAL	**359.381**		**1.188.785**		**829.404**	

The increased staff needs, which amount to € 344 million, can be explained by the table below:

Staff Cost Comparison
(All figures in Euro '000)

	Initial forecast – COM (2003)	in %	**Updated forecast – May 2006**	in %	**Difference**	in %
Evaluation tasks	16.525	9%	150.226	28%	133.701	39%
Authorisations, restrictions and committee work	58.562	31%	169.355	32%	110.793	32%
Non-dossier driven tasks such as helpdesk, REACH related training, and access to information	19.099	10%	64.371	12%	45.272	13%
Pre-registration, registration, downstream-user notifications, PPORD applications, etc.	48.510	25%	48.809	9%	298	0%
Support of the Appeal Body	4.868	3%	10.407	2%	5.539	2%
Administrative Directorate	32.246	17%	68.068	13%	35.822	10%
Office of the Executive Director	11.191	6%	23.779	4%	12.588	4%
GRAND TOTAL	**191.002**		**535.015**		**344.013**	

Please note that the costs related to the increased tasks for pre-registration have been off-set by reduced costs for registrations. As the work on the operational IT system is progressing it is now clear that the registration process will be largely automated and therefore it was possible to reduce the required manual workload in the financial model.

ANNEX III
ESTABLISHMENT PLAN
Permanent and non permanent staff

	Grade	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
Executive Director (AD15/16)	AD15/16	1	6	7	8	8	8	8	8	8	8	8	8	8	8	8
Director	AD14	2														
Head of Unit	AD13	8	15	25	25	25	25	25	27	26	25	25	25	24	23	22
Head of Sector / Team leader	AD12	8														
DO-Group leader	AD11	8														
Senior DO, experienced specialist	AD10	8														
Senior DO, specialists; less experienced	AD9	9	103	156	225	237	258	258	194	189	139	152	274	227	224	224
DO, junior expert	AD8	10														
DO; junior expert	AD7	9														
DO new, experienced	AD6	8														
DO new, un-	AD5	4														

experienced																
	AST11	0														
Personal ass. of ED	AST10	1														
Personal ass. of Directors	AST9	2	54	66	68	71	71	70	70	71	70	70	73	71	72	71
Senior Assistant Committees, HR, Finance	AST8	6														
Senior Assistant Administration, operation	AST7	6														
Assistant/senior secretary of ED	AST6	1														
Senior secretary of Directors	AST5	1														
Secretary of HoU	AST4	8	70	101	111	115	114	111	113	111	105	107	121	115	114	111
Secretary	AST3	1														
	AST2	0														
	AST1	0														
		101	**248**	**355**	**437**	**456**	**476**	**472**	**412**	**405**	**347**	**362**	**501**	**445**	**441**	**436**