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Advancing REACH Financing options for ECHA

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Advancing REACH
Financing options for ECHA

Final report of work package 7

by

Anthony Footitt and Daniel Venkovsky
RPA, Loddon

Dirk Jepsen, Antonia Reihlen
Ökopol GmbH, Hamburg

On behalf of the German Environment Agency

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Publisher
Umweltbundesamt
Wörlitzer Platz 1
06844 Dessau-Roßlau
Tel: +49 340-2103-0
Fax: +49 340-2103-2285
info@umweltbundesamt.de
Internet: www.umweltbundesamt.de

/umweltbundesamt.de
/umweltbundesamt

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RPA Ltd.
1 Beccles road
NR14 6LT Loddon
United Kingdom

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Abstract: Development of REACH – Financing options for ECHA

The report considers the activities carried out by the European Chemicals Agency (ECHA) to implement REACH and CLP to date, the expenditure needed to sustain this work and the funding structure of the Agency as background to the consideration of how new finance concepts could be adopted to finance ECHA's activities after 2018 in the short term (4 years), medium term (10 years) and longer term (15-20 yeas). A number of new funding mechanisms which could be introduced into the discussions at EU level are proposed and fee levels estimated. These include: **A new annual charge/fee requirement:** This measure builds on the original 'one off' registration fee and converts it into a fee charged on an annual basis that covers the ongoing costs of the regulator (ECHA), to undertake its activities under REACH/CLP. This could replace existing fees for updates (and so no update fees would apply) or, alternatively, existing fees for updates could remain in place; **A new update requirement:** this would require periodic updates to be made to registration dossiers with the aim of increasing the quality of dossiers while increasing revenue to ECHA from update fees; **Implement charges for updates triggered by ECHA evaluation:** this option would seek to pass on the costs of the evaluation to registrants found to be non-compliant by raising charges connected with non-compliant endpoints.

Kurzbeschreibung: REACH-Weiterentwicklung – Optionen zur Finanzierung der ECHA

In diesem Bericht werden aufbauend auf Informationen über die aktuellen Aktivitäten der Europäischen Chemikalienagentur (ECHA) zur Umsetzung von REACH und der CLP-Verordnung, über die zur Aufrechterhaltung dieser Arbeiten notwendigen Ausgaben sowie über die Finanzierungsstruktur der Agentur genutzt, um Konzepte zur Finanzierung der ECHA nach 2018 kurzfristig (4 Jahre), mittelfristig (10 Jahre) und langfristig (15-20 Jahre) abzuleiten. Einige neue Finanzierungsmechanismen und die dazu notwendigen Gebührenhöhen werden abgeschätzt, um sie in die Diskussionen auf EU-Ebene einzubringen. Unter anderem wird vorgeschlagen: **Eine neue jährliche Abgabe/verpflichtende Gebühr**: Diese Maßnahme würde die ursprünglich geplante, einmalige Registrierungsgebühr in eine jährlich zu entrichtende Gebühr umwandeln, welche die laufenden Kosten der ECHA für Arbeiten unter REACH/CLP abdeckt. Die jährliche Gebühr könnte die Aktualisierungsgebühren ablösen (Aktualisierungen von Registrierungen wären also kostenfrei) oder zusätzlich erhoben werden; **eine neue Anforderung zur Aktualisierung von Registrierungsdossiers**: Diese wiederkehrende Verpflichtung zur Aktualisierung von Registrierungsdossiers hätte das Ziel, die Informationsqualität zu erhöhen und gleichzeitig ein Einkommen für die ECHA zu generieren; und **Gebühren für Dossieraktualisierungen, die durch Bewertungen der ECHA erforderlich werden**: Diese Option würde bezwecken, dass die Kosten einer Dossierbewertung an die Registranten weitergegeben werden, deren Registrierungsdossiers nicht gesetzeskonform sind, indem die Gebührenhöhe mit den nicht-konformen Endpunkten korreliert wird.

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List of abbreviations

C&L	Classification and labelling
CLP	Classification, labelling and packaging
COM	The European Commission
CPVO	Community Plant Variety Office
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
EASA	European Aviation Safety Agency
EBA	European Banking Authority
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EDA	European Defence Agency
EEA	European Environment Agency
EFSA	European Food Safety Authority
EFTA	European Free Trade Agreement
EIOPA	European Insurance and Occupational Pensions Authority
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EMSA	European Maritime Safety Agency
ERA	European Union Agency for Railways
ESMA	European Securities and Markets Authority
ETF	European Training Foundation
EU	European Union
EUIPO	European Union Intellectual Property Office
EU-LISA	European Agency for the operational management of large-scale IT systems in the area of freedom, security and justice
EUON	European Union Observatory for Nanomaterials
FRA	European Union Agency for Fundamental Rights
GSA	European Global Navigation Satellite Systems Agency
IT	Information technology
MSCAs	Member State Competent Authorities
OECD	Organisation for Economic Cooperation and Development
PIC	Prior Informed Consent (Regulation)
PPORD	Product and process orientated research and development notification
(Q)SAR	(Quantitative) Structure Activity Relationship
REACH	Registration, evaluation, authorisation and restriction of chemicals
REACH IT	The central IT system used to securely submit, process and manage data and dossiers

SatCen	European Union Satellite Centre
SDS	Safety Data Sheet
SME	Small, medium and large enterprises
SRB	Single Resolution Board
SVHC	Substance of very high concern

Summary

The aim of this study is to propose a concept to finance ECHA's activities to implement REACH and CLP in a mid-term perspective (i.e. until 2023 and until 2028), which can be introduced into the discussions at EU level.

ECHA's key roles and responsibilities

The European Chemicals Agency (ECHA) was originally established under Article 75 of the REACH Regulation ((EC) 1907/2006) for *the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of this [the REACH] Regulation and to ensure consistency at Community level in relation to these aspects*. As such, it officially came into existence when REACH came into force (1 June 2007), becoming officially autonomous from the European Commission on 1 January 2008.

Being established by the REACH Regulation, ECHA's structure and function in relation to REACH is enshrined within that regulation. In respect of REACH, its main duties and activities cover substance registration, dossier and substance evaluation and Authorisation and Restriction. ECHA also has duties and responsibilities in respect of the Classification, labelling and packaging of substances and mixtures (CLP) regulation (1272/2008) the main activities consisting of provision of technical guidance on classification and labelling, handling and assessing proposals for harmonised classifications and processing C&L notifications and maintaining the C&L inventory.

ECHA also has duties and responsibilities in respect of the Biocides regulation (528/2012) and the Prior informed consent (PIC) regulation (649/2012) as well as other work that is outside the scope of regulation per se. These activities were outside the scope of this study – which is focussed on activities and funding on REACH and CLP alone.

In addition, the Commission and the European legislator have requested that ECHA take over additional responsibilities in the future. These include the creation of a new database on substances of very high concern (SVHC) under the Waste Framework Directive or the creation of a searchable database for information on mixtures in case of emergency health response. To date, no additional budget is foreseen for these additional responsibilities. If none is forthcoming this will put further pressure on ECHA's resources and further increase the need to secure supplementary funding.

Expenditure and funding of REACH/CLP activities to date

ECHA is required to report its accounts and budgets and these are organised under the following formal titles:

- **Operating expenditure** – the cost of operational activities and time spent broken down by task under the relevant legislation; and
- **Staff and buildings** – the costs of assets and other overheads associated with the organisation as a whole. To the extent possible, this is apportioned to the different legislative activities where, as noted above, from 2014, separate apportioning between REACH/CLP and PIC/Biocides was introduced.

Figure A provides an overview of total expenditure under these headings as set out in ECHA's budget reports for the relevant years[1]. As can be seen from the figure, the data suggests that total annual expenditure appears to be typically around the €94-95 million per year mark. Operational expenditure makes up around 25% of this.

Funding for ECHA's work on REACH/CLP activities

ECHA's activities in relation to both REACH and CLP are funded by a combination of revenue from fees and charges balanced with an EU subsidy and contributions from Member States and EFTA.

The nature of fees for registration, authorisation and appeals under REACH is defined in Article 74 of the REACH Regulation and the levels are set out in the Fee Regulation ((EC) 340/2008 as modified by (EC) 2015/864). Similarly, CLP fees are defined in the CLP Regulation and the levels are set in the CLP fee regulation ((EC) 440/2010).

In addition to these fees, Articles 11 and 13(4) of the REACH fee Regulation ((EC) 340/2008) also allow fees and charges to be levied for services other than those listed in Article 74 of REACH. All fees for REACH and CLP are differentiated by size of company to ensure that smaller companies (with smaller turnover) are not affected disproportionately relative to large companies.

Revenue from fees and EU budget contributions to date

Figure B provides data on balance of contributions between fees and EU budget contributions from 2008 to 2018. Data for 2018 are taken from the most recent amending budget (21 September 2018). Accounts and Budgets record fee income differently with the former recording the actual fee income received and the latter (budget) recording the fee income budgeted for spending that year. As such, the accounts record fee income from the 2010 registration deadline (for substances manufactured or imported in quantities of >1000t) as around €356 million. This 2010 fee income, combined with receipts for the 2013 registration deadline (for 100-1000t substances) sustained the Agency for the years 2010[2] to 2015 inclusive with no balancing contribution required from the EU budget until 2016.

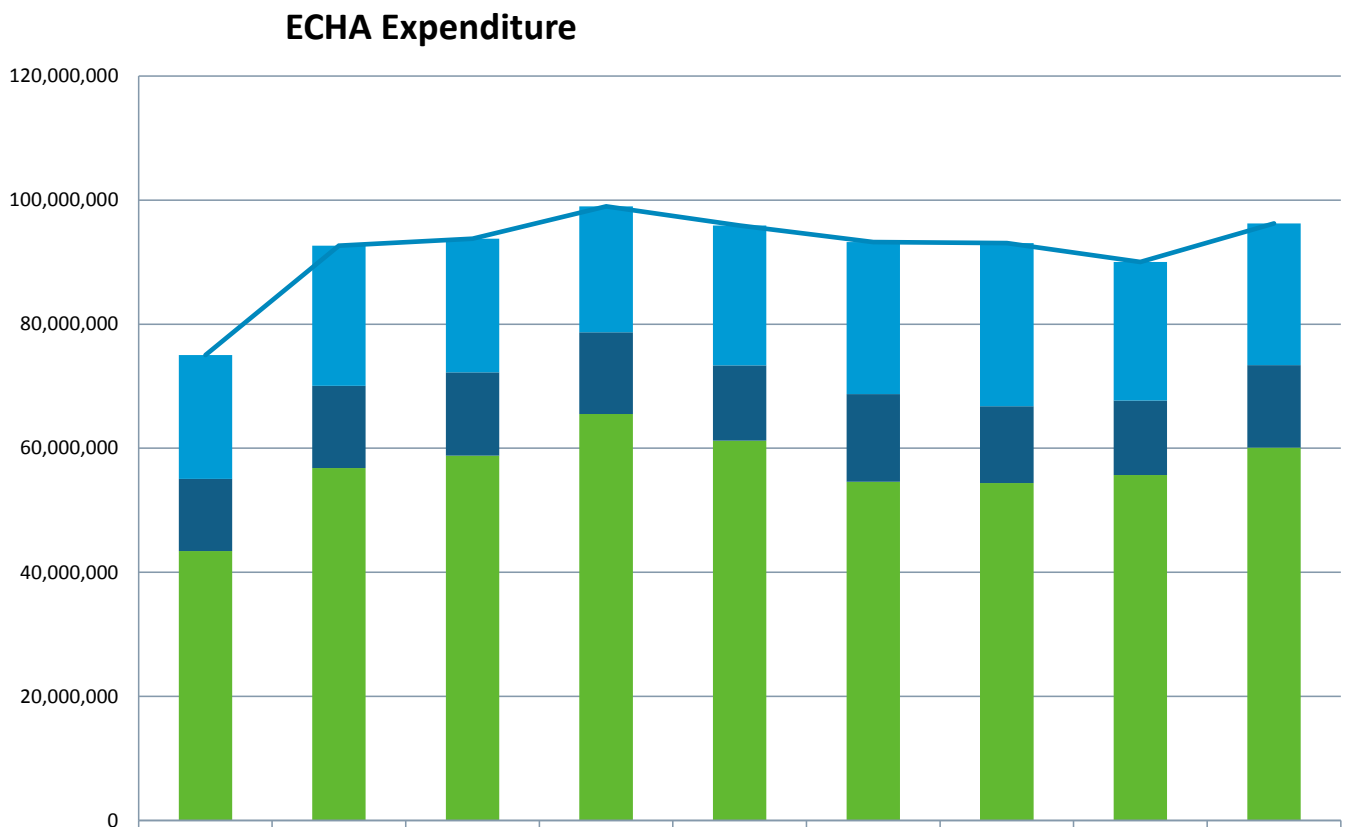
In all, for the years 2009-2016 total fee income was of the order of €584 million and EU budget contributions were of the order of €120 million which, combined with additional contributions from EEA and individual Member States, covered a total expenditure of around €730 million (excluding direct expenditure in relation to Biocides and PIC).

Around 90% of the fee income to date has been from Registration fees. The passing of the final 2018 registration deadline largely ends the significant revenue stream seen from registration. The €77million income from Registration 2018 is sufficient only to fund ECHA's activities for 2018 and not successive years in the way that was the case with fee income from Registration 2010.

[1] https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

[2] The balancing contribution from the EU budget for 2010 was refunded to the Commission in 2011 and the figures on EU budget contribution in the figure have been adjusted accordingly.

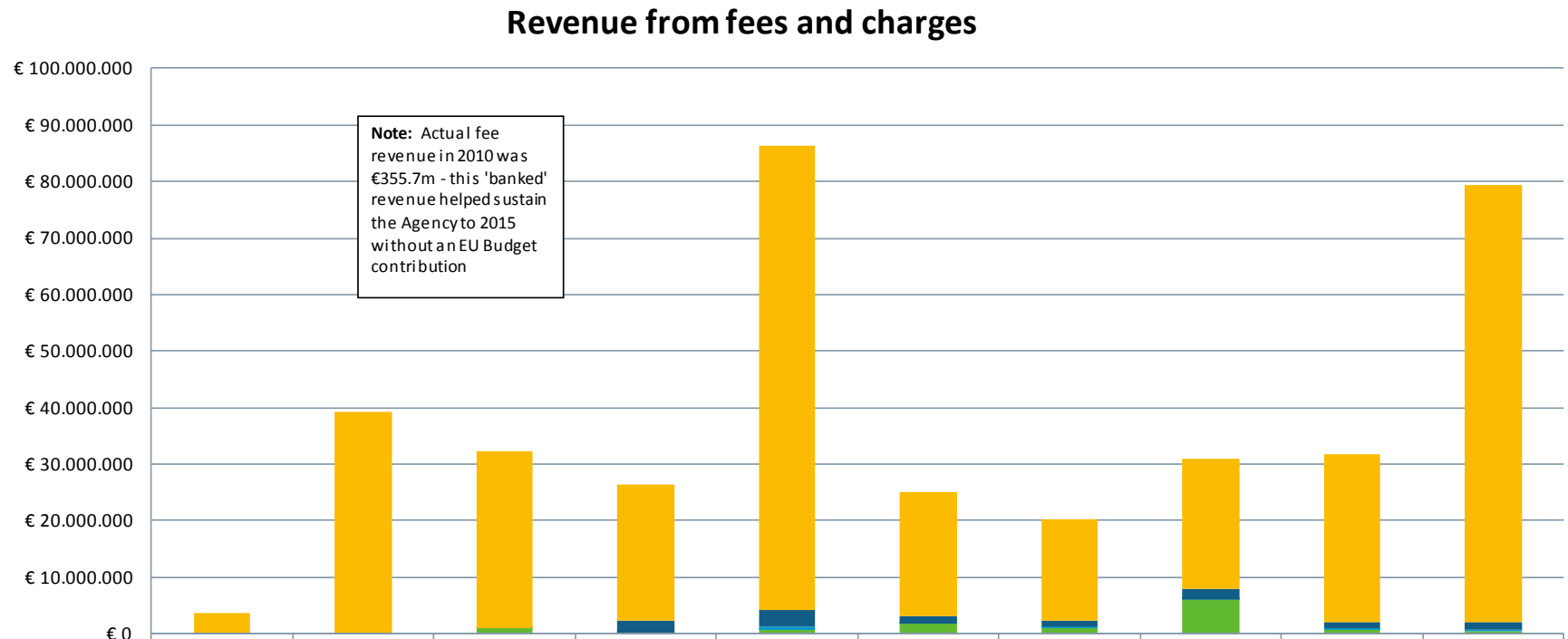
Figure A: ECHA's total REACH/CLP expenditure



	2010	2011	2012	2013	2014	2015	2016	2017	2018
REACH operating expenditure	19,959,224	22,612,718	21,558,626	20,256,354	22,581,400	24,495,700	26,309,440	22,356,362	22,825,148
Building, equipment and miscellaneous operating expenditure	11,624,281	13,220,000	13,397,100	13,170,600	12,100,320	14,101,605	12,347,132	11,983,639	13,285,047
Staff	43,426,635	56,824,782	58,811,180	65,537,300	61,234,020	54,618,876	54,412,542	55,683,201	60,121,356
Total	75,010,140	92,657,500	93,766,906	98,964,254	95,915,740	93,216,181	93,069,114	90,023,201	96,231,551

Source: ECHA budget report. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Figure B: ECHA's revenue from fees and charge



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Registration	€ 3.473.000	€ 38.976.700	€ 31.200.000	€ 24.000.000	€ 82.000.000	€ 22.077.004	€ 17.955.000	€ 23.210.566	€ 29.553.000	€ 77.308.000
Other fees and charges	€ 0	€ 0	€ 0	€ 2.000.000	€ 3.000.000	€ 1.200.000	€ 1.000.000	€ 1.750.000	€ 1.233.700	€ 1.357.000
CLP	€ 0	€ 0	€ 80.000	€ 68.000	€ 510.000	€ 100.000	€ 229.000	€ 144.000	€ 148.613	€ 148.000
Appeals	€ 120.000	€ 230.000	€ 130.000	€ 50.000	€ 134.640	€ 80.000	€ 7.069	€ 14.244	€ 14.315	
Authorisation	€ 0	€ 0	€ 900.000	€ 180.000	€ 600.000	€ 1.682.000	€ 1.066.000	€ 5.961.449	€ 714.661	€ 570.077

Source: ECHA accounts and budget reports. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Future scenarios for ECHA's expenditure and revenue

The original 2006 expectation was that post registration 2018 ECHA would be able to progress through completeness checks, substance evaluation, identification and authorisation SVHCs and restrictions etc., with a slowly diminishing list of tasks and substances. The reality, however, seems to be not as anticipated in 2006. For example, the Commission's REACH Review[3] identified that "*progress towards the objectives is lagging behind initial expectations*" and that non-compliance of registration dossiers was one of (the four) issues requiring most urgent action. This implies a continuing need for expenditure at around current levels (around €100million) for the next four years (at least) if the political objectives of REACH and CLP are to be met, as anticipated.

On this basis, the study has made some tentative estimates of ECHA's future expenditure and revenue under over the following time periods:

- Short term - 4 years from present
- Mid-term – 10 years from present
- Longer-term - 15-20 years from present.

Tentative projections have been made on the basis of available information including complete registration data that has been kindly supplied by ECHA. These data have been used to calculate different cost elements by considering the numbers of dossiers in the registration database and associated effort per unit of work.

Clearly, the further into the future one seeks to project, the more uncertain will be the estimates. The starting point has been a baseline scenario for REACH/CLP activities reflecting expected outcomes. The assumptions and variables for each component of expenditure have also been used to generate estimates of revenue from fees and charges associated with that work.

In addition to the baseline two alternative scenarios have also been developed to calculate the expenditure (and fees) associated with the following changes in dossier:

- evaluation expanded to all >1000t substances using current screening strategy; and
- evaluation expanded to all >1000t substances using higher levels of scrutiny.

For each of these alternative scenarios the following two sub-scenarios have been calculated based on variations in both timescale and the dossiers that are selected:

- evaluation is expanded to all >1000t dossiers (lead, member and individual submissions) over a 20 year period; and
- evaluation is expanded to >1000t dossiers from lead and individual registrants only over a 10 year period.

ECHA's expenditure under the baseline and scenarios

-

[3] https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

ECHA's revenue from REACH/CLP fees and charges

Figure D provides matching data on expected revenue generated under the baseline and the different scenarios. In all periods and under all scenarios, fees under the heading of registration and updates make up the vast majority (90% and more) of fee income. The decline in income from the present to the longer-term is almost entirely due to the completion of registration of phase-in substances in 2018. The bulk of continuing income under all scenarios (again around 90%) is owing to a low level of new substance registrations (which is the same across all scenarios) and fees for updates. The latter (updates) varies from one scenario to another and this is responsible for the vast majority of the variation between scenarios because of the link between evaluations and updates.

Here, increased and expanded evaluation of >1000t substances, while requiring additional expenditure (as described in the previous section), also generates more updates to correct errors and gaps which, in turn, generates more fees. These same evaluation decisions generate more appeals for which fees are also charged.

Figure C provides ECHA's estimated total expenditure under the baseline and each of the scenarios. The projections suggest that under the baseline scenario costs fall from around €90m per year in the present/short term to around €77m per year in the longer term. Some of these cost reductions are due to changing work and expenditure requirements over the short, medium and long-term, some of the operational cost elements are likely to remain largely the same as at present. For example, expenditure on scientific IT tools is likely to remain fairly constant at the present level of circa €10m per year because continuing update and maintenance of REACH IT and other tools is likely to be necessary into the future to preserve functionality and maintain the security of the data.

With the exception of costs for evaluation and registration and datasharing, the operational costs under all four alternative scenarios are identical to those under the baseline. As such, any variation in the total expenditure between the baseline and each of the scenarios is associated only with:

- The increased efforts required for evaluation to be expanded to all >1000t substances (where this varies from one scenario to another);
- The increased work that this expanded evaluation activity generates in relation to registration work. Here, the evaluations are likely to identify failings in dossiers that need to be corrected via dossier updates. This work comes under the title of registration, datasharing and dissemination and, so, there is an increase in workload under this title; and
- Changes in staff and building costs consistent with increased efforts above.

ECHA's revenue from REACH/CLP fees and charges

Figure D provides matching data on expected revenue generated under the baseline and the different scenarios. In all periods and under all scenarios, fees under the heading of registration and updates make up the vast majority (90% and more) of fee income. The decline in income from the present to the longer-term is almost entirely due to the completion of registration of phase-in substances in 2018. The bulk of continuing income under all scenarios (again around 90%) is owing to a low level of new substance registrations (which is the same across all scenarios) and fees for updates. The latter (updates) varies from one scenario to another and

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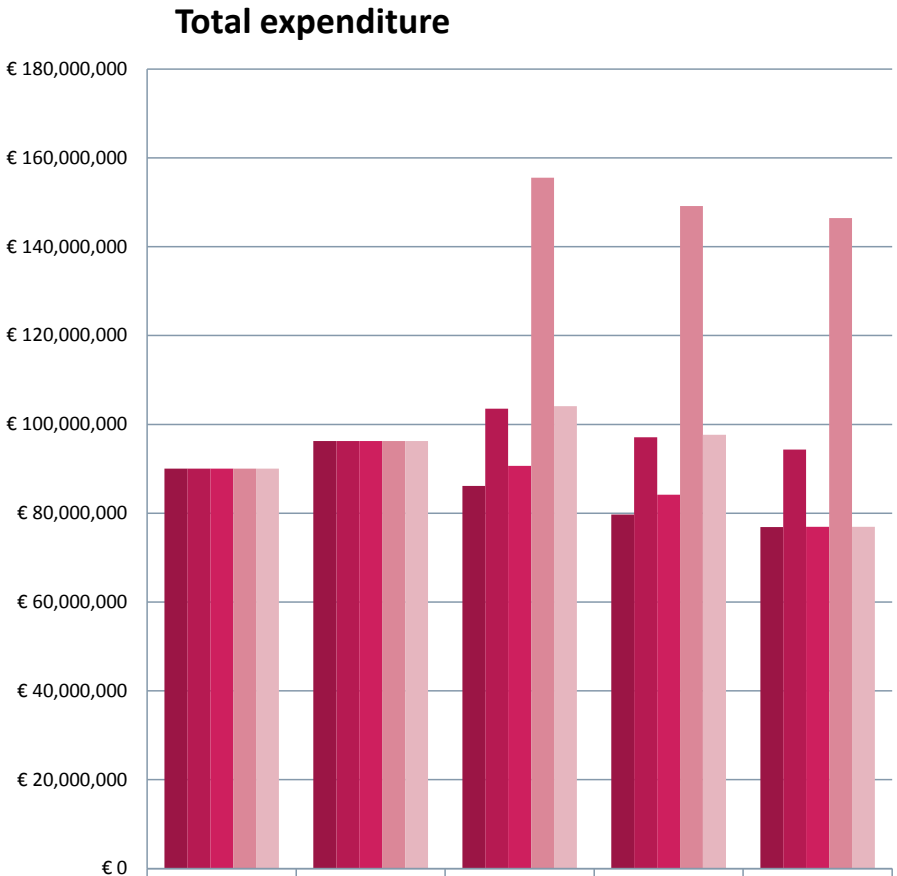
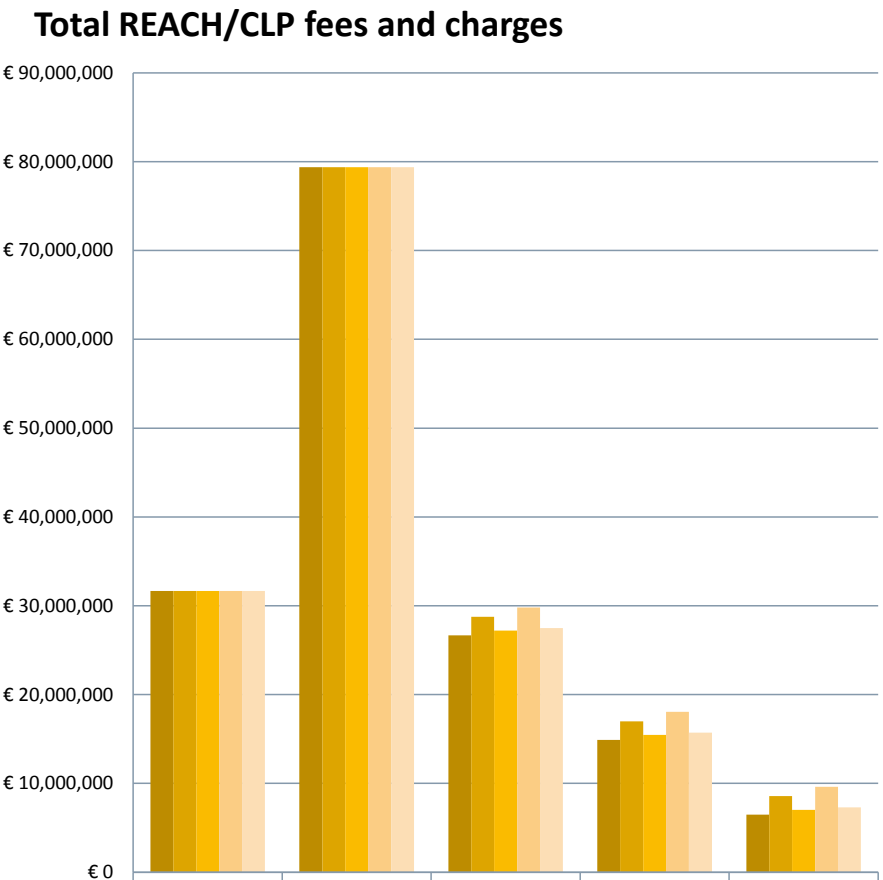
Figure C: Estimated total ECHA expenditure under the scenarios



	2017	2018	Short	Medium	Long
Baseline	€ 90,023,201	€ 96,231,551	€ 86,147,000	€ 79,678,000	€ 76,908,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - all dossiers over 20 years	€ 90,023,201	€ 96,231,551	€ 103,504,000	€ 97,087,000	€ 94,347,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - lead and individual dossiers over 10 years	€ 90,023,201	€ 96,231,551	€ 90,646,000	€ 84,188,000	€ 76,935,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - all dossiers over 20 years	€ 90,023,201	€ 96,231,551	€ 155,532,000	€ 149,138,000	€ 146,415,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - lead and individual dossiers over 10 years	€ 90,023,201	€ 96,231,551	€ 104,121,000	€ 97,677,000	€ 76,951,000

Source: For 2017-2018, ECHA budget reports. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Figure D: Estimated total ECHA revenue from REACH/CLP fees and charges under the scenarios



	2017	2018	Short	Medium	Long
Baseline	€ 31,664,289	€ 79,383,077	€ 26,667,000	€ 14,909,000	€ 6,488,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - all dossiers over 20 years	€ 31,664,289	€ 79,383,077	€ 28,758,000	€ 16,996,000	€ 8,576,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - lead and individual dossiers over 10 years	€ 31,664,289	€ 79,383,077	€ 27,210,000	€ 15,450,000	€ 7,030,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - all dossiers over 20 years	€ 31,664,289	€ 79,383,077	€ 29,809,000	€ 18,045,000	€ 9,626,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - lead and individual dossiers over 10 years	€ 31,664,289	€ 79,383,077	€ 27,485,000	€ 15,725,000	€ 7,305,000

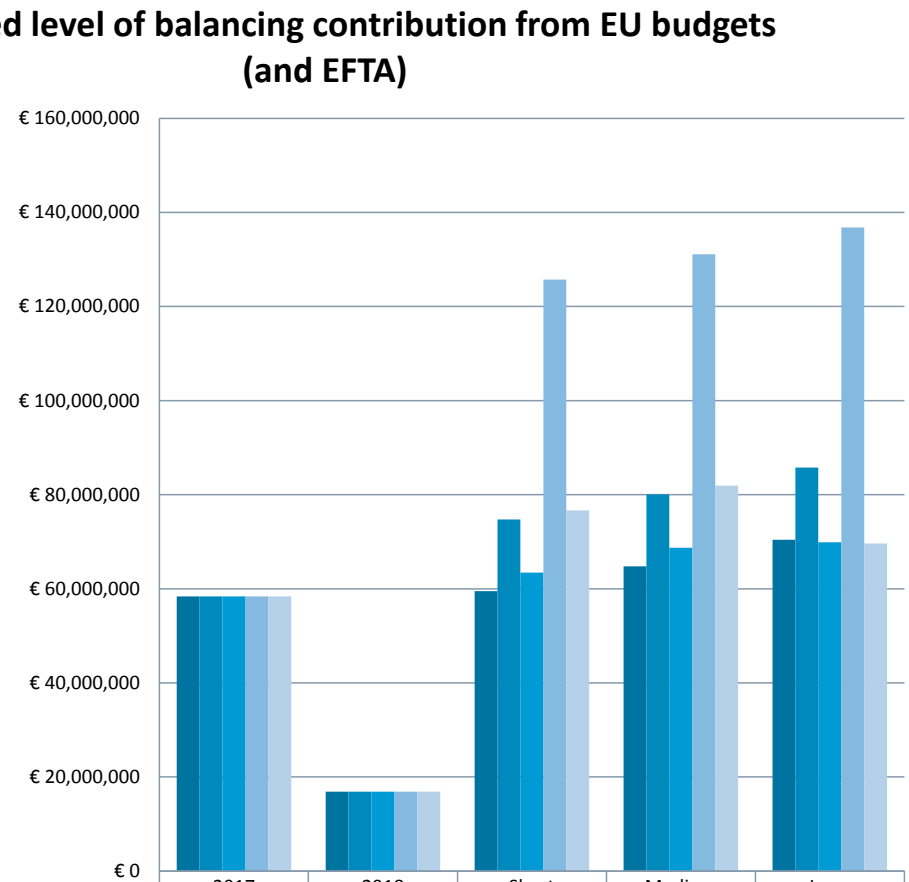
Source: For 2017-2018, ECHA budget reports. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Balancing the budget

From the discussion above on ECHA expenditure under the baseline and scenarios and the revenue from fees and charges it is clear that there is a large gap between the two. Under the current arrangements this gap is filled by the commitment to fund the deficit from a contribution from the EU budget. The magnitude of the EU budget contributions required to fill the deficits under the baseline and scenarios is provided as Figure E.

As can be seen from these data, under the baseline and all scenarios an increase or a substantial increase in EU budget contributions is required to ensure continued support of ECHA to achieve the political objectives of REACH.

Figure E: EU Balancing Budget contributions under the scenarios



	2017	2018	Short	Medium	Long
Baseline	€ 58,358,912	€ 16,848,474	€ 59,480,000	€ 64,769,000	€ 70,420,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - all dossiers over 20 years	€ 58,358,912	€ 16,848,474	€ 74,746,000	€ 80,091,000	€ 85,771,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - lead and individual dossiers over 10 years	€ 58,358,912	€ 16,848,474	€ 63,436,000	€ 68,738,000	€ 69,905,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - all dossiers over 20 years	€ 58,358,912	€ 16,848,474	€ 125,723,000	€ 131,093,000	€ 136,789,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - lead and individual dossiers over 10 years	€ 58,358,912	€ 16,848,474	€ 76,636,000	€ 81,952,000	€ 69,646,000

Source: For 2017-2018, ECHA budget reports. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Future Finance options

Given the significant gap between the revenue from fees and charges for REACH/CLP and expenditure on REACH/CLP under all scenarios the study has considered several alternative approaches and mechanisms that would increase revenue from ECHA activities and, in the process reduce/eliminate the gap (and therein the EU budget contribution), and correct the

obvious imbalance between the cost of ensuring compliance with REACH (and the objectives of REACH) and the revenue from the fee mechanisms that were originally envisaged.

When considering how this might be achieved the study has sought to draw on (and ensure that options are consistent with) funding models of other EU agencies. As part of the study, a review of funding methods applied in other EU has been undertaken. This review is provided as Appendix B to this report.

On the basis of these findings and consideration of the mechanisms and objectives of REACH/CLP the following alternatives have been considered:

- **A new annual charge/fee requirement:** where existing fee mechanisms were intended (Article74(3) REACH) to cover the costs of completeness and compliance checking, evaluation, etc. the evidence presented in the report suggests that they do/have not. This measure builds on the original 'one off' registration fee and converts it into fee charged on an annual basis that covers the ongoing costs of the regulator (ECHA), to undertake its activities under REACH/CLP. The magnitude of annual fees to generate an illustrative €100m of revenue per year have been calculated and presented in Table A. €100m per year has been used as a target figure not only because it would make a substantial contribution but also because it is simple to interpolate alterative fees for other target levels of revenue (e.g. 50% of the fees in Table A would deliver €50m per year). These fees could be used in addition to current fees for updates or could replace existing fees for updates. The latter might be more consistent with encouraging (or rather not discouraging) submission of updates to dossiers. Here it should be noted that the Commission's recent REACH Review[4] identified that non-compliance of registration dossiers was one of (the four) issues requiring most urgent action and "*encourage updating of registration dossiers*" is Action 1 from the Review. Eliminating fees for updates under the baseline would reduce total fee revenue by around €11m;

Table A: Annual fee per dossier to deliver €100million per year

Company size Type of registration	Large	Medium	Small	Micro
1-10t	€ 199	€ 129	€ 70	€ 10
10-100t	€ 535	€ 348	€ 187	€ 27
100-1000t	€ 1,432	€ 931	€ 501	€ 72
>1000t	€ 3,860	€ 2,509	€ 1,351	€ 193
Intermediate	€ 174	€ 113	€ 61	€ 9

- **A new regular update requirement:** A new requirement could be introduced that would require periodic updates to be made to registration dossiers. The aim of this would be to increase the quality of dossiers (consistent with the findings of the Commission's REACH Review identified above) while increasing revenue to ECHA from update fees. Three different scenarios for update frequency were considered: 3, 5 and 10 year. The revenue

[4] https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

generated was estimated based on a constant flow of updates (as opposed to bulk submissions coinciding with the update frequency). The total revenue generated and the distribution of fee costs (not cost of updating) between companies of different sizes is provided in Table B. As can be seen from the table, as update frequency is currently (estimated to be) around 10% per year under the baseline, this is equivalent to an update frequency of 10 years and so revenue, in the short term, is likely to be the same/similar. In the longer term under the baseline, however, if the frequency of annual updates to dropped below 10% under the baseline there would be a reduction in fee revenue from updates in the future. This would not occur with an obligatory 10 year update but, at the same time, the revenue generated is still unlikely to offset the total expenditure and the EU budget contributions. A three year update frequency would generate more revenue but even this is relatively modest compared with ECHA expenditure and the EU budget contributions.

Table B: Revenue and industry costs from new requirements to periodically update dossiers

Update frequency (years)	Total fee revenue	Large enterprises	Medium enterprises	Small enterprises	Micro enterprise
Current	**€ 10,959,199**	€ 10,126,197	€ 660,287	€ 106,120	€ 66,595
3	**€ 36,530,664**	€ 33,753,991	€ 2,200,956	€ 353,732	€ 221,984
5	**€ 21,918,398**	€ 20,252,395	€ 1,320,574	€ 212,239	€ 133,190
10	**€ 10,959,199**	€ 10,126,197	€ 660,287	€ 106,120	€ 66,595

- **Implement charges for updates triggered by ECHA evaluation:** Connected with the scenarios for extending evaluation to all >1000t substances (as opposed to the legislative minimum target of 5% of dossiers), this option seeks to address the issue that the work required by ECHA to identify weaknesses and non-compliance with dossiers through evaluation is intensive and time consuming and that the cost of these undertaken are not recouped by the fees charged for updates at present. The option has not been costed owing to time and budget constraints. However, some consideration has been given to how such charges could be implemented and their level set. Here, rather than introduce a totally new system of fees the report suggests application of an update fee multiplier for situations where an update is required owing to non-compliance identified by ECHA (as opposed to an update by a registrant out of their own initiative). If this multiplier were, for example, 5, then the update fee due for ECHA identified non-compliance would be 5 times that for one submitted by the registrant on their own initiative. Such an 'evaluation update charge multiplier' would encourage registrants to comply with their existing legal obligations, ensuring that their dossiers are up to date, conform to the requirements and appropriately penalise those that do not.
- **Introduce charging for access to 'enhanced' data services:** ECHA are in possession of a large amount of data and provide access to a number of online databases. As part of the study we have given some consideration to how and what ECHA could charge for access to using, for example, a 'pay wall'. This option was found to be problematic, however. Articles 118 and Article 119 of REACH are clearly set out that all available information should be

made freely available online. In addition, the availability of (free) information is important to delivering the political objectives of REACH. As such, charging for any data that is useful to that end is not consistent with the objectives of REACH and ECHA's duties. As such, the option was eliminated and not considered in detail.

Zusammenfassung

Ziel der Studie ist es, ein Konzept zur mittelfristigen (d. h. bis 2023 bzw. 2028) Finanzierung der Aktivitäten der ECHA zur Umsetzung von REACH und CLP zu erarbeiten, welches in die Diskussion auf EU-Ebene eingebracht werden kann.

Die zentralen Rollen und Verantwortlichkeiten der ECHA

Die Europäische Chemikalienagentur (ECHA) wurde ursprünglich gemäß Artikel 75 der REACH-Verordnung ((EG) 1907/2006) "*Für die Verwaltung und in einigen Fällen die Durchführung der technischen, wissenschaftlichen und administrativen Aspekte dieser* [der REACH-]*Verordnung und zur Gewährleistung der Einheitlichkeit in diesen Bereichen"* gegründet und ist offiziell seit dem 1. Januar 2008 von der Europäischen Kommission unabhängig.

Da sie im Rahmen der REACH-Verordnung gegründet wurde, entsprechen die Struktur und Funktionen der ECHA den Aufgaben in der Verordnung und sind in derselben beschrieben. Die wichtigsten Pflichten und Aktivitäten der ECHA unter REACH liegen im Bereich der Registrierung, der Dossier- und Stoffbewertung, der Zulassung sowie der Beschränkung. Die ECHA ist zudem auch für die Umsetzung der Verordnung zur Einstufung und Kennzeichnung von Stoffen und Gemischen (CLP) (EG 1272/2008) zuständig. Die Aufgaben liegen hier im Bereich der Bereitstellung technischer Leitlinien zur Einstufung und Kennzeichnung, des Managements und der Bewertung von Vorschlägen zur harmonisierten Einstufung, der Bearbeitung von Meldungen zur Einstufung und Kennzeichnung sowie der Pflege des Einstufungsverzeichnisses.

Zudem ist die ECHA mit der Umsetzung der Biozid-Verordnung (528/2012), der Verordnung zur Ein- und Ausfuhr gefährlicher Chemikalien (649/2012) sowie mit an diese EU-Gesetzgebungen angrenzenden Arbeitsbereichen befasst. Diese Aktivitäten wurden in dieser Studie nicht betrachtet, da sie sich auf die Arbeit und Finanzierung der ECHA in Bezug auf REACH und CLP beschränkt.

Die Kommission und der europäische Gesetzgeber haben die ECHA zudem verpflichtet, in Zukunft weitere Aufgaben zu übernehmen, u. a. die Erstellung einer Datenbank über besonders besorgniserregende Stoffe (SVHC) unter der Abfallrahmenrichtlinie und einer Datenbank mit Informationen über Gemische für gesundheitliche Notfälle (Giftinformationszentren). Derzeit ist hierfür kein Budget vorgesehen und wenn keine entsprechende Finanzierung bereitgestellt wird, erhöht sich der Druck auf die Ressourcen der ECHA und die Dringlichkeit, neue Finanzierungsquellen zu erschließen.

Aktuelle Ausgaben und Finanzierung von REACH-/CLP-Aktivitäten

Die ECHA muss über ihren Haushalt Bericht erstatten. In ihren Berichten werden zwei Haushaltstitel unterschieden. Das sind:

- **Laufende Betriebsausgaben** – die Kosten der laufenden Aktivitäten und die dafür aufgewendete Zeit ist entsprechend der in der Gesetzgebung definierten, relevanten Aufgabenbereiche aufgeschlüsselt – und
- **Personal und Gebäude** –die Sachkosten und weitere Gemeinkosten, die durch die ECHA als Ganzes verursacht werden. Soweit möglich, werden diese Kosten auf die jeweiligen Gesetzgebungen verteilt, wobei zwischen REACH/CLP und PIC/Biozide seit 2014 unterschieden wird.

Abbildung A zeigt die nach diesen beiden Haushaltstiteln aufgeteilten Gesamtausgaben, so wie sie in den Haushaltsberichten der ECHA für die jeweiligen Jahre[5] aufgeführt sind. Die Abbildung zeigt, dass die jährlichen Gesamtausgaben ca. 94-95 Mio. Euro betragen, wovon ca. 25 % auf die laufenden Betriebsausgaben entfallen.

Finanzierung der Arbeiten der ECHA zu REACH und CLP

Die Aktivitäten der ECHA zur Umsetzung von REACH und CLP werden durch eine Kombination von Einnahmen aus Gebühren und Abgaben finanziert, welche durch Ausgleichszahlungen der EU und Beiträge der Mitgliedstaaten sowie der EFTA ergänzt werden.

Die Art der Gebühren für Registrierungen, Zulassungen und Widersprüche unter REACH sind in Artikel 74 der REACH-Verordnung definiert. Ihre Höhe ist in der Gebührenverordnung ((EG) 340/2008, geändert durch die Verordnung (EG) 2015/864) festgelegt. In ähnlicher Weise sind die Gebühren für Aktivitäten zur Einstufung und Kennzeichnung in der CLP-Verordnung definiert und ihre Höhen in der CLP-Gebührenverordnung ((EG) 440/2010) festgelegt.

Zusätzlich zu diesen Gebühren erlauben Art. 11 und Art. 13(4) der REACH-Gebührenverordnung ((EG) 340/2008) die Erhebung von Gebühren und Abgaben für die Nutzung von Dienstleistungen, die nicht in REACH Artikel 74 aufgeführt sind. Alle Gebühren unter REACH und CLP sind nach Unternehmensgröße differenziert, um zu gewährleisten, dass kleine Unternehmen (mit geringerem Umsatz) im Verhältnis zu großen Unternehmen nicht überproportional hoch belastet werden.

Einnahmen aus Gebühren und Beiträge aus dem EU-Budget bis dato

Abbildung B zeigt das Verhältnis der Finanzierungsanteile aus Gebühren und aus dem EU-Haushalt für die Jahre 2008 bis 2018. Die Daten für 2018 sind dem aktuellsten Anpassungshaushalt entnommen (21. September 2018). Die Summen für die Kostenstellen und für die Haushaltstitel werden unterschiedlich ermittelt: Erstere enthalten die tatsächlich eingenommenen Gebühren und letztere zeigen, mit welchen Einnahmen jeweils gerechnet wurde. Die Kostenstellen weisen die Gebühreneinnahmen seit der Registrierungsfrist 2010 (für Hersteller und Importeure von Stoffen in Volumina >1000 t/a) mit ungefähr 356 Mio. Euro aus. Die Gebühren aus 2010 finanzierten, zusammen mit den Einnahmen aus der Registrierung bis 2013 (Stoffe zwischen 100 und 1000 t/a), die Agentur in den Jahren 2010[6] bis einschließlich 2015. Es wurde kein Beitrag aus dem EU-Haushalt bis 2016 benötigt.

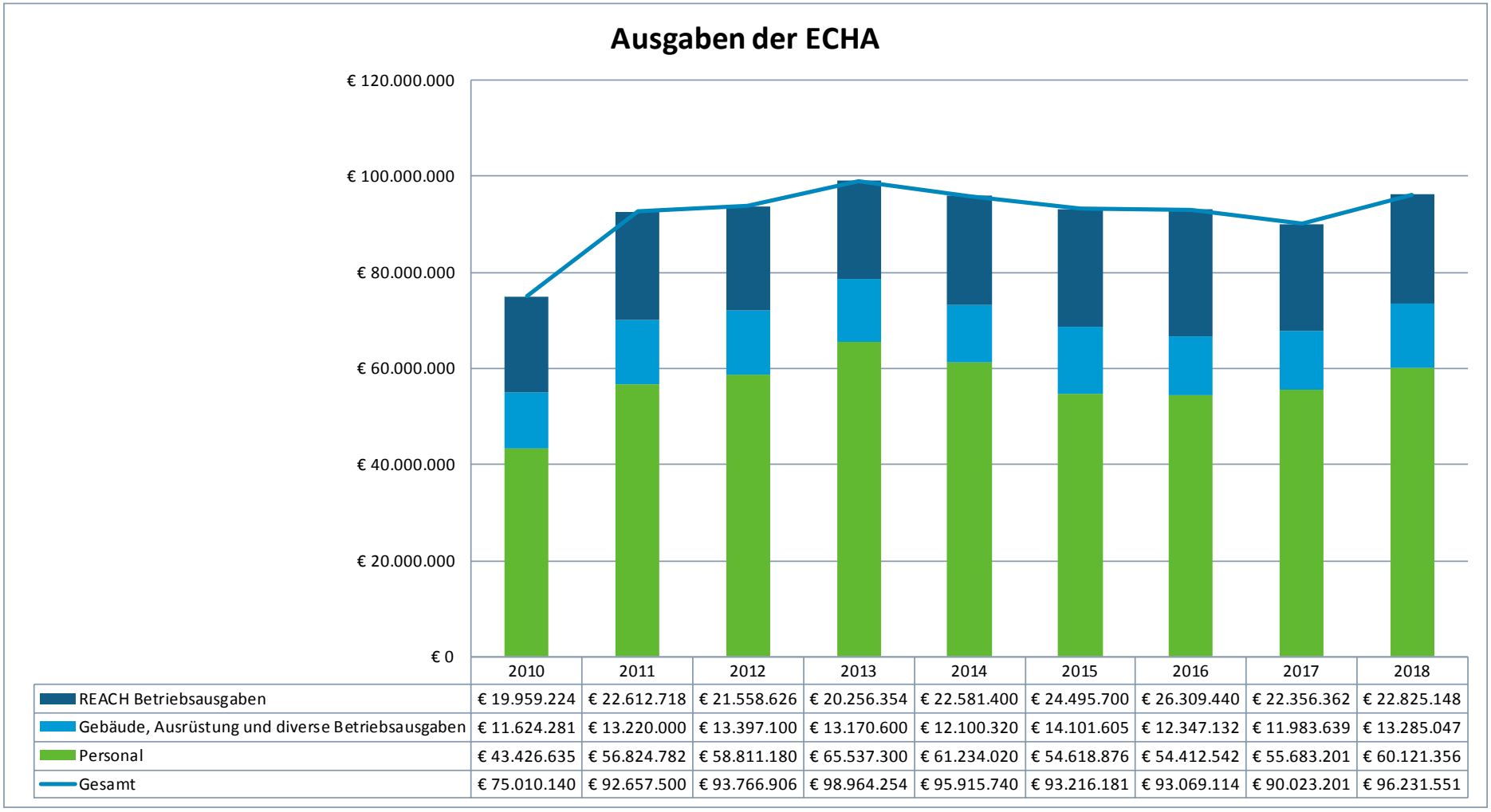
Insgesamt wurden in den Jahren 2009 bis 2016 durch Gebühren ca. 584 Mio. Euro eingenommen. Zusammen mit den Beiträgen aus dem EU-Haushalt von ca. 120 Mio. Euro und der EEA sowie einzelner Mitgliedstaaten konnten die Gesamtausgaben von ca. 730 Mio. Euro vollständig gedeckt werden (direkte Ausgaben für Biozide und die Import-/Exportverordnung sind hierbei nicht eingeschlossen).

Bis dato kamen 90 % der Einnahmen der ECHA aus den Registrierungsgebühren. Nach Ende der letzten Registrierungsfrist in 2018 wird dieser, signifikante Einkommensstrom enden. Die Aktivitäten der ECHA in 2018 und den folgenden Jahren sind durch die Einnahmen von 77 Mio. Euro aus der letzten Registrierungsphase nicht annähernd so zu finanzieren, wie es in den vorherigen Zeiträumen der Fall war.

[5] https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

[6] Die Ausgleichszahlungen aus dem EU-Budget für 2010 wurde der Kommission in 2011 zurückgezahlt und die Zahlen des EU-Budgets wurden in der Abbildung entsprechend angepasst.

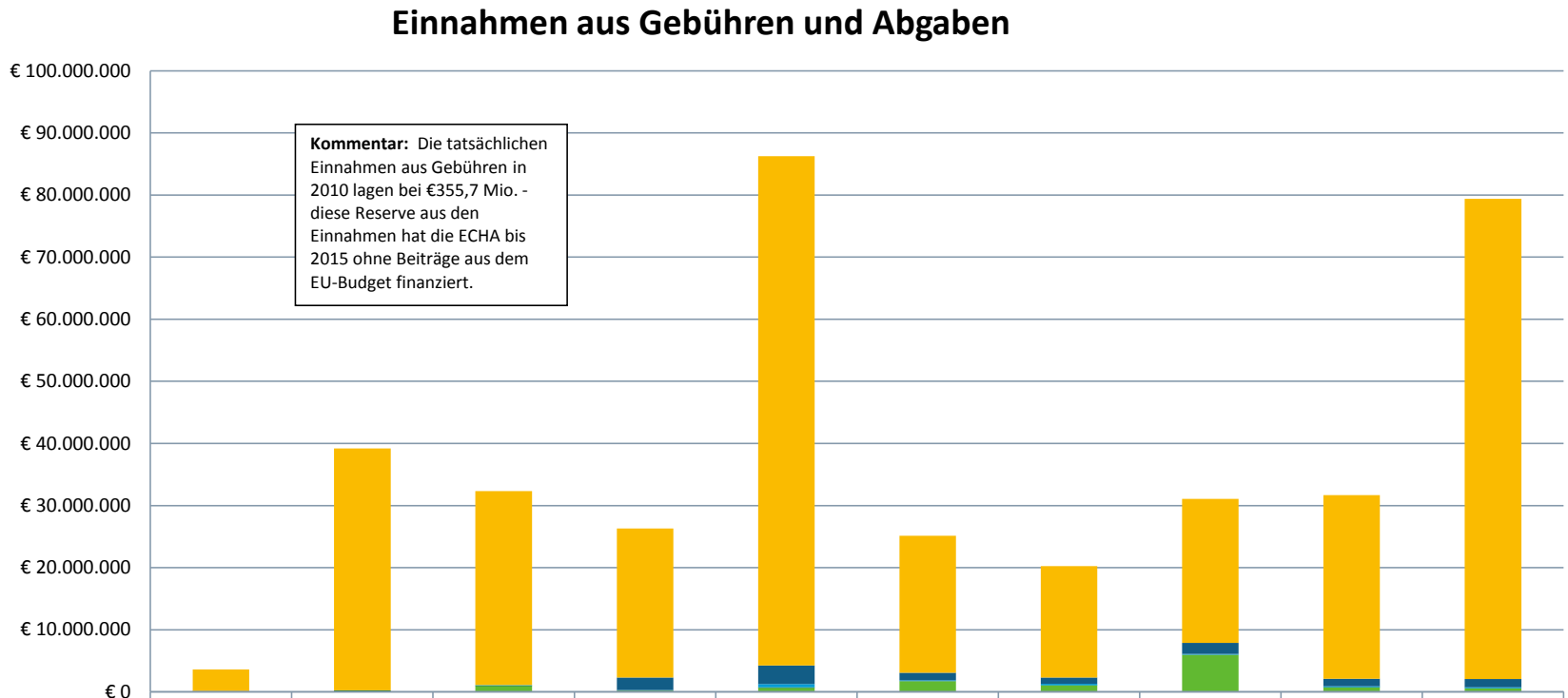
Abbildung A: Gesamtausgaben der ECHA für REACH/CLP



	2010	2011	2012	2013	2014	2015	2016	2017	2018
REACH Betriebsausgaben	€ 19.959.224	€ 22.612.718	€ 21.558.626	€ 20.256.354	€ 22.581.400	€ 24.495.700	€ 26.309.440	€ 22.356.362	€ 22.825.148
Gebäude, Ausrüstung und diverse Betriebsausgaben	€ 11.624.281	€ 13.220.000	€ 13.397.100	€ 13.170.600	€ 12.100.320	€ 14.101.605	€ 12.347.132	€ 11.983.639	€ 13.285.047
Personal	€ 43.426.635	€ 56.824.782	€ 58.811.180	€ 65.537.300	€ 61.234.020	€ 54.618.876	€ 54.412.542	€ 55.683.201	€ 60.121.356
Gesamt	€ 75.010.140	€ 92.657.500	€ 93.766.906	€ 98.964.254	€ 95.915.740	€ 93.216.181	€ 93.069.114	€ 90.023.201	€ 96.231.551

Quelle: ECHA Haushaltsberichte. Siehe https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Abbildung B: Einnahmen der ECHA aus den Finanz- und Budgetberichten



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Registrierung	€ 3.473.000	€ 38.976.700	€ 31.200.000	€ 24.000.000	€ 82.000.000	€ 22.077.004	€ 17.955.000	€ 23.210.566	€ 29.553.000	€ 77.308.000
Andere Gebühren und Abgaben	€ 0	€ 0	€ 0	€ 2.000.000	€ 3.000.000	€ 1.200.000	€ 1.000.000	€ 1.750.000	€ 1.233.700	€ 1.357.000
CLP	€ 0	€ 0	€ 80.000	€ 68.000	€ 510.000	€ 100.000	€ 229.000	€ 144.000	€ 148.613	€ 148.000
Appeals	€ 120.000	€ 230.000	€ 130.000	€ 50.000	€ 134.640	€ 80.000	€ 7.069	€ 14.244	€ 14.315	
Zulassung	€ 0	€ 0	€ 900.000	€ 180.000	€ 600.000	€ 1.682.000	€ 1.066.000	€ 5.961.449	€ 714.661	€ 570.077

Quelle: ECHA Finanz- und Haushaltsberichte. Siehe https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Zukunftsszenarien für die Ausgaben und Einnahmen der ECHA

Ursprünglich wurde erwartete, dass die ECHA nach der Registrierungsfrist 2018 in der Lage sein würde, sich durch Dossier- und Stoffbewertungen, die SVHC-Identifizierung und Zulassungen sowie Beschränkungen etc. zu finanzieren. Es wurde auch davon ausgegangen, dass sich die Liste der Aufgaben und Stoffe langsam verkürzt. In der Realität scheint es jedoch anders zu sein als 2006 angenommen: Unter anderem beschreibt die EU-Kommission in ihrem REACH-Review[7], dass *"[…] ihre Ziele langsamer erreicht werden als ursprünglich erwartet, […]"* und dass die fehlende Konformität der Registrierungsdossiers einer der vier Bereiche ist, der am dringendsten bearbeitet werden muss. Das impliziert, dass zur Erreichung der politischen Ziele von REACH und CLP (mindestens) für die nächsten vier Jahre einen Finanzierungsbedarf ungefähr auf dem aktuellen Niveau (ca. 100 Mio. Euro) besteht.

In dieser Studie werden erste Abschätzungen gemacht, wie hoch die zukünftigen Ausgaben der ECHA sein könnten und welche Einnahmen sie in den folgenden Zeiträumen erzielen würde:

- kurzfristig – die nächsten 4 Jahre,
- mittelfristig – die nächsten 10 Jahre und
- langfristig – die nächsten 15 bis 20 Jahre.

Auf Basis der von der ECHA freundlicherweise bereitgestellten vollständigen Daten aus der Registrierung und weiteren verfügbaren Informationen, wurde die Höhe einzelner Kostenelemente berechnet, indem aus der Anzahl der Registrierungsdossiers und dem Aufwand pro Aktivität die Kosten pro Arbeitseinheit ermittelt wurden.

Es ist offensichtlich, dass die Unsicherheiten der Schätzungen größer werden, je weiter man versucht, in die Zukunft zu projizieren. Startpunkt der Berechnungen ist das Basisszenario, welches die aktuellen Erwartungen an die Kosten- und Einnahmeentwicklung darstellt. Die Annahmen und Variablen für jedes Element der Ausgabenschätzungen wurden auch dazu genutzt, Werte für die Einnahmen aus Gebühren und Abgaben abzuleiten, die mit den Arbeiten verbunden sind.

Zusätzlich zum Basisszenario wurden zwei alternative Szenarien entwickelt, um die Ausgaben (und Gebühren) zu berechnen, die mit den folgenden Veränderungen in der Dossierbewertung einhergehen würden: Ausweitung der Dossierbewertung auf alle Stoffe >1000 t/a

- unter Anwendung der aktuellen Screening-Strategie und
- durch Detailbewertung mit deutlich höherer Bewertungstiefe.

Für jedes der alternativen Szenarien wurden die folgenden zwei Unterszenarien gebildet, welche sich sowohl bezüglich der Zeiträume als auch der Art der geprüften Dossiers unterscheiden. Die Bewertung wird ausgeweitet auf:

- alle Dossiers für Stoffe >1000 t/a, also die von federführendem Registrant, allen Mitregistranten sowie alle Einzeldossiers, über einen Zeitraum von 20 Jahren und
- nur die Dossiers für Stoffe >1000 t der federführenden Registranten und die Einzeldossiers über einen Zeitraum von 10 Jahren.

[7] https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

Ausgaben der ECHA im Basisszenario und in den alternativen Szenarien

Abbildung C zeigt die Gesamtausgaben der ECHA im Basisszenario und in den alternativen Szenarien. Im Basisszenario fallen die Kosten von derzeit ca. 90 Mio. Euro pro Jahr im kurzfristigen Szenario auf ca. 77 Mio. Euro pro Jahr in der langfristigen Perspektive. Einige der verringerten Ausgaben entstehen durch veränderte Arbeitsweisen und Anforderungen im kurzfristigen, mittelfristigen und langfristigen Zeitraum während sich die Höhe der laufenden Kosten wahrscheinlich kaum gegenüber heute unterscheiden wird. Zum Beispiel werden die Ausgaben für die wissenschaftlichen IT-Instrumente wahrscheinlich konstant auf dem aktuellen Niveau von ca. 10 Mio. Euro pro Jahr bleiben, da es auch zukünftig notwendig sein wird, die IT-Instrumente kontinuierlich zu aktualisieren und zu pflegen, um sicher zu stellen, dass ihre Funktionalität sowie die Sicherheit der Daten erhalten bleibt.

Mit Ausnahme der Kosten für die Bewertung, die Registrierung und die Datenteilung, sind die laufenden Ausgaben in allen vier Szenarien genauso hoch wie im Basisszenario. Daher sind die Unterschiede bei den Gesamtausgaben zwischen Basisszenario und den alternativen Szenarien lediglich verursacht durch

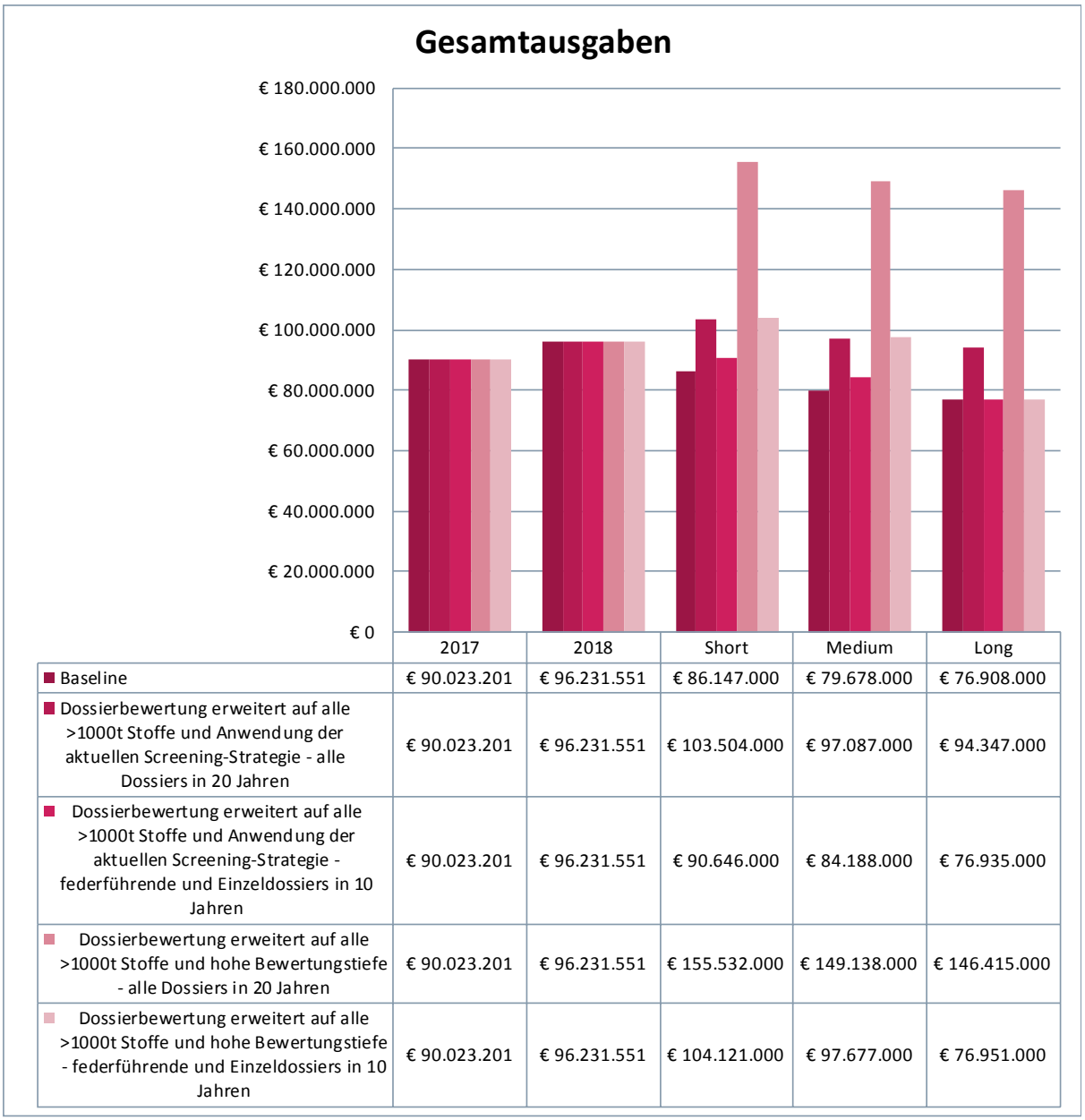
- erhöhte Aufwendungen für die Ausweitung der Bewertung auf alle Stoffe, die in Mengen größer 1000 t/a registriert werden (Umfang der Ausweitung variiert in den Szenarien) und
- erhöhte Aufwendungen, welche im Bereich der Registrierung durch die erweiterten Bewertungen entstehen. Die Bewertungen werden voraussichtlich Defizite in den Dossiers aufdecken, die im Rahmen von Aktualisierungen korrigiert werden. Die dafür notwendigen Arbeiten der ECHA fallen unter den Titel „Registrierung, Datenteilung und Veröffentlichung“ und erhöhen ihn daher entsprechend.
- Veränderungen in den Kosten für Personal und Gebäude, die mit dem erhöhten Arbeitsaufwand konsistent sind.

Einnahmen der ECHA für REACH/CLP aus Gebühren und Abgaben

Abbildung D illustriert die erwarteten Einnahmen im Basisszenario und in den alternativen Szenarien. In allen Zeiträumen und in allen Szenarien machen die Registrierungsgebühren den größten Anteil (90 % und mehr) der Gebühreneinnahmen aus. Der wichtigste Grund für die Verringerungen der Einnahmen von jetzt bis zum Langzeitszenario, ist der Abschluss der Registrierung von phase-in Stoffen in 2018. Die verbleibenden, wenigen Registrierungen (in allen Szenarien gleich) sowie die Gebühren für Dossieraktualisierungen machen den größten Anteil (wiederum ca. 90 %) der kontinuierlichen Einnahmen in allen Szenarien aus. Da sich die Anzahl der Aktualisierungen in Abhängigkeit von der Anzahl der Dossierbewertungen verändert, unterscheiden sich die Szenarien entsprechend der definierten Bewertungsniveaus (Umfang, Detailtiefe, Zeitraum) auch in der Anzahl der Aktualisierungen.

Die Erweiterung der Dossierbewertung für Stoffe >1000 t/a erfordert einerseits im Vergleich zum Basisszenario zusätzliche Ausgaben (wie im vorigen Kapitel beschrieben) und erzeugt andererseits eine höhere Aktualisierungsrate, damit Fehler korrigiert und Lücken geschlossen werden. Dies generiert wiederum Einnahmen aus Gebühren. Die Bewertungsentscheidungen verursachen außerdem mehr Widersprüche, wodurch ebenfalls Gebühren anfallen.

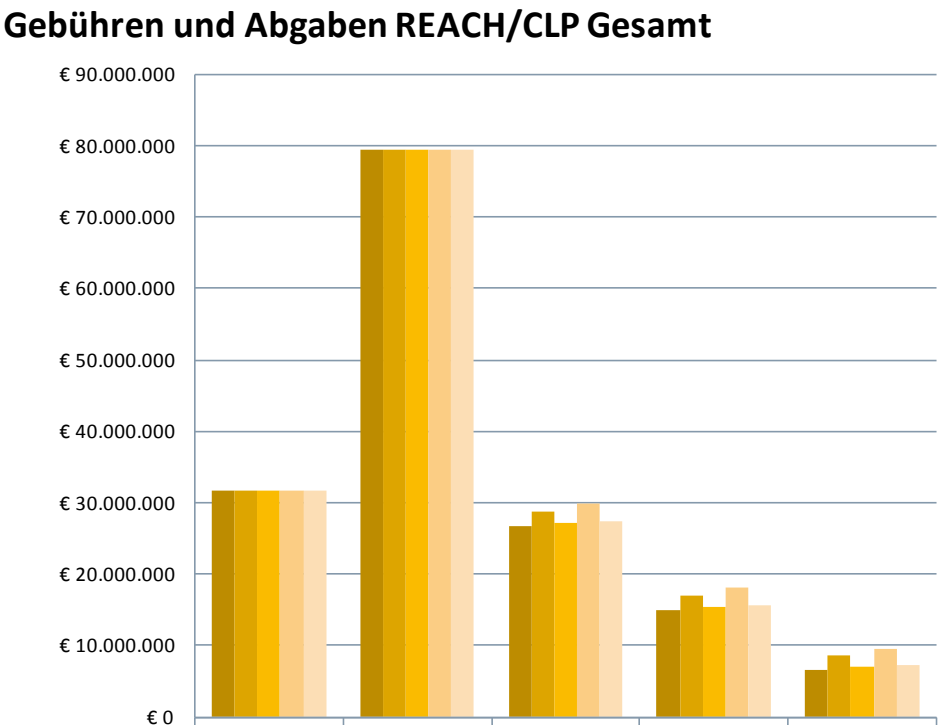
Abbildung C: Geschätzte Gesamtausgaben der ECHA in den Szenarien



	2017	2018	Short	Medium	Long
Baseline	€ 90.023.201	€ 96.231.551	€ 86.147.000	€ 79.678.000	€ 76.908.000
Dossierbewertung erweitert auf alle >1000t Stoffe und Anwendung der aktuellen Screening-Strategie - alle Dossiers in 20 Jahren	€ 90.023.201	€ 96.231.551	€ 103.504.000	€ 97.087.000	€ 94.347.000
Dossierbewertung erweitert auf alle >1000t Stoffe und Anwendung der aktuellen Screening-Strategie - federführende und Einzeldossiers in 10 Jahren	€ 90.023.201	€ 96.231.551	€ 90.646.000	€ 84.188.000	€ 76.935.000
Dossierbewertung erweitert auf alle >1000t Stoffe und hohe Bewertungstiefe - alle Dossiers in 20 Jahren	€ 90.023.201	€ 96.231.551	€ 155.532.000	€ 149.138.000	€ 146.415.000
Dossierbewertung erweitert auf alle >1000t Stoffe und hohe Bewertungstiefe - federführende und Einzeldossiers in 10 Jahren	€ 90.023.201	€ 96.231.551	€ 104.121.000	€ 97.677.000	€ 76.951.000

Quelle: Für 2017–2018, ECHA Haushaltsberichte. Siehe https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Abbildung D: Geschätzte Gesamteinahmen der ECHA aus Gebühren und Abgaben für REACH/CLP in den verschiedenen Szenarien



	2017	2018	Kurz	Mittel	Lang
Baseline	€ 31.664.289	€ 79.383.077	€ 26.667.000	€ 14.909.000	€ 6.488.000
Dossierbewertung erweitert auf alle >1000t Stoffe und Anwendung der aktuellen Screening-Strategie - alle Dossiers in 20 Jahren	€ 31.664.289	€ 79.383.077	€ 28.758.000	€ 16.996.000	€ 8.576.000
Dossierbewertung erweitert auf alle >1000t Stoffe und Anwendung der aktuellen Screening-Strategie - federführende und Einzeldossiers in 10 Jahren	€ 31.664.289	€ 79.383.077	€ 27.210.000	€ 15.450.000	€ 7.030.000
Dossierbewertung erweitert auf alle >1000t Stoffe und hohe Bewertungstiefe - alle Dossiers in 20 Jahren	€ 31.664.289	€ 79.383.077	€ 29.809.000	€ 18.045.000	€ 9.626.000
Dossierbewertung erweitert auf alle >1000t Stoffe und hohe Bewertungstiefe - federführende und Einzeldossiers in 10 Jahren	€ 31.664.289	€ 79.383.077	€ 27.485.000	€ 15.725.000	€ 7.305.000

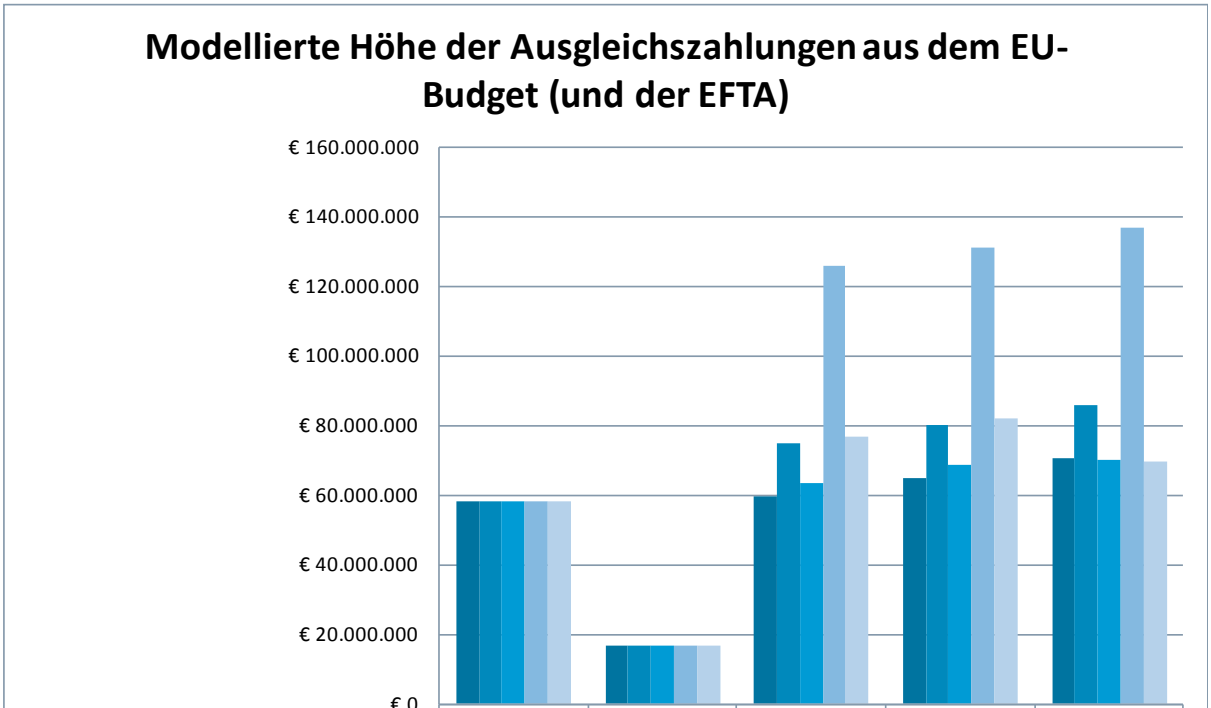
Quelle: Für 2017–2018, ECHA Haushaltsberichte. Siehe https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Ausgleich des Budgets

Die in den vorherigen Kapiteln dargestellten Informationen zu den Einnahmen durch Gebühren/Abgaben und den Ausgaben der ECHA im Basisszenario und den alternativen Szenarien verdeutlichen, dass es zukünftig eine große Finanzierungslücke gibt. Gemäß den aktuellen Vereinbarungen werden Defizite der ECHA durch Beiträge aus dem EU-Haushalt finanziert. Die Höhe der zur Schließung der Finanzierungslücke notwendigen Ausgleichs-zahlungen ist für die unterschiedlichen Szenarien in der Abbildung E dargestellt.

Hieraus wird ersichtlich, dass sowohl im Basisszenario als auch in den alternativen Szenarien ein (substanziell) höherer Beitrag der EU erforderlich ist, um sicherzustellen, dass die ECHA die Erreichung der politischen Ziele von REACH kontinuierlich unterstützen kann.

Abbildung E: Modellierte Höhe der Ausgleichszahlungen aus dem EU-Budget



	2017	2018	Short	Medium	Long
Baseline	€ 58.358.912	€ 16.848.474	€ 59.480.000	€ 64.769.000	€ 70.420.000
Dossierbewertung erweitert auf alle >1000t Stoffe und Anwendung der aktuellen Screening-Strategie - alle Dossiers in 20 Jahren	€ 58.358.912	€ 16.848.474	€ 74.746.000	€ 80.091.000	€ 85.771.000
Dossierbewertung erweitert auf alle >1000t Stoffe und Anwendung der aktuellen Screening-Strategie - federführende und Einzeldossiers in 10 Jahren	€ 58.358.912	€ 16.848.474	€ 63.436.000	€ 68.738.000	€ 69.905.000
Dossierbewertung erweitert auf alle >1000t Stoffe und hohe Bewertungstiefe - alle Dossiers in 20 Jahren	€ 58.358.912	€ 16.848.474	€ 125.723.000	€ 131.093.000	€ 136.789.000
Dossierbewertung erweitert auf alle >1000t Stoffe und hohe Bewertungstiefe - federführende und Einzeldossiers in 10 Jahren	€ 58.358.912	€ 16.848.474	€ 76.636.000	€ 81.952.000	€ 69.646.000

Quelle: Für 2017–2018, ECHA Haushaltsberichte. Siehe https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

Optionen für die zukünftige Finanzierung

Angesichts der signifikanten Lücke zwischen den Einnahmen aus Gebühren und Abgaben und den Ausgaben für REACH/CLP, die in allen berücksichtigten Szenarien auftritt, wurden verschiedene alternative Herangehensweisen und Mechanismen zur Verbesserung der Einnahmesituation untersucht. Die Optionen sollten die Finanzierungslücke (und damit den Beitrag aus dem EU-Haushalt) verringern/überflüssig machen und das offensichtliche Ungleichgewicht zwischen den zur Sicherstellung der REACH-Konformität (und der Erreichung

der Ziele) notwendigen Ausgaben und den Einnahmen aus den vorhandenen Gebührenmechanismen korrigieren.

In den Überlegungen, wie dies erreicht werden kann (und um Konsistenz mit anderen Bereichen in der EU sicherzustellen), wurden in dieser Studie die Finanzierungsmodelle anderer EU-Agenturen untersucht. Diese Analyse findet sich im Anhang B.

Basierend auf diesen Ergebnissen und unter Berücksichtigung der Verfahren und Zielsetzungen von REACH und der CLP-Verordnung wurden die folgenden alternativen Finanzierungsoptionen untersucht:

- **Anforderung für eine neue, jährliche Abgabe/Gebühr:** Die Berechnungen in dieser Studie verdeutlichen, dass die bisher vorgesehenen Gebühren (REACH Artikel 74(3)) zur Finanzierung der Kosten für die Vollständigkeits- und Konformitätsprüfung sowie die Bewertungsverfahren, in der Praxis nicht ausreichen. Die Option einer neuen, jährlichen Abgabe für Registrierungsdossiers basiert auf der ursprünglichen „Einmalzahlung" für eine Registrierung und wandelt diese in eine jährliche Gebühr um. Hierdurch sollten die laufenden Kosten der ECHA abgedeckt werden, die für die Umsetzung von REACH/CLP notwendig sind. Die berechnete Höhe einer jährlichen Abgabe, welche beispielsweise eine Einnahme von 100 Mio. Euro pro Jahr generieren würde, ist in Tabelle A dargestellt. Die Summe von 100 Mio. Euro wurde nicht nur deshalb gewählt, weil sie einen substanziellen Beitrag zur Finanzierung erbringen würde, sondern auch, weil alternative Gebührenhöhen zu anderen Zieleinnahmen daraus einfach interpoliert werden können (z. B. 50 % der in Tabelle A aufgeführten Gebühren würden 50 Mio. Euro Einnahmen pro Jahr generieren). Die jährliche Abgabe könnte entweder zusätzlich zu den gültigen Aktualisierungsgebühren eingeführt werden oder diese ersetzen. Die zweite Variante wäre konsistenter, da sie die Aktualisierung von Dossiers eher fördert (bzw. nicht davon abschreckt). Es ist zu beachten, dass die Kommission in ihrem aktuellen REACH-Review Bericht[8] ausführt, dass die mangelnde Konformität der Registrierungsdossiers mit den REACH-Anforderungen einer der (vier) Aspekte ist, welche am dringlichsten zu bearbeiten und zu beheben sind: Die "*Förderung der Aktualisierung der Registrierungsdossiers*" ist die erste Maßnahme im Bericht. Die Streichung der Gebühren für Dossieraktualisierungen würde im Basisszenario die Einnahmen um ca. 11 Mio. Euro verringern;

Tabelle A: Jährliche Gebühren pro Dossier, die 100 Mio. Euro pro Jahr einbringen würden

Unternehmensgröße Art des Stoffes	Große Unternehmen	Mittlere Unternehmen	Kleine Unternehmen	Kleinstunter-nehmen
1-10 t	€ 199	€ 129	€ 70	€ 10
10-100 t	€ 535	€ 348	€ 187	€ 27
100-1000 t	€ 1.432	€ 931	€ 501	€ 72
>1000 t	€ 3.860	€ 2.509	€ 1.351	€ 193
Zwischenprodukt	€ 174	€ 113	€ 61	€ 9

[8] https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

- **Neue Anforderung für regelmäßige Aktualisierungen:** Diese Option beinhaltet die Einführung einer Pflicht, Registrierungsdossiers regelmäßig zu aktualisieren, mit dem Ziel die Dossierqualität zu verbessern (was zu den Aussagen der Kommission im REACH-Review passt) und die Einnahmen der ECHA aus Aktualisierungsgebühren zu erhöhen. Drei verschiedene Szenarien bzgl. der Aktualisierungshäufigkeit wurden betrachtet: 3, 5 und 10 Jahre. Zur Abschätzung der Einnahmen wurde angenommen, dass die Dossiers kontinuierlich aktualisiert werden (es käme also nicht kurz vor Ablauf von Fristen zu starken Häufungen von Aktualisierungen). Die Einnahmen aus der Aktualisierung und die jeweilige Höhe der Gebühren (nicht die Kosten für die Aktualisierung selbst) entsprechend der Größen der Unternehmen sind in Tabelle B dargestellt.
  Im Basisszenario wird mit einer (angenommenen) Aktualisierungsrate von aktuell 10 % der Dossiers pro Jahr gerechnet. Dies entspricht einer Aktualisierungsfrequenz von 10 Jahren (und damit dem dritten Szenario). Das heißt, die (aktuellen) Einnahmen (Basisszenario) sollten mehr oder weniger mit denen aus dem Szenario mit der niedrigsten Aktualisierungs-frequenz übereinstimmen. Fiele im Basisszenario die Aktualisierungsrate unter 10 % pro Jahr, würden sich die Einnahmen aus den Gebühren in der Zukunft verringern. Das geschähe im Szenario mit der Aktualisierungsfrequenz von 10 Jahren hingegen nicht. Dennoch ist es unwahrscheinlich, dass die Einnahmen aus Aktualisierungen die Kosten der ECHA decken und Ausgleichszahlungen aus dem EU-Haushalt überflüssig machen würden. Eine Aktualisierungspflicht alle drei Jahre würde zwar mehr Einnahmen generieren, diese wären jedoch im Vergleich zu den Ausgaben der ECHA und den Beiträgen aus dem EU-Haushalt eher gering.

Tabelle B: Einnahmen und Kosten für die Industrie durch eine neue Anforderung für regelmäßige Aktualisierungen der Registrierungsdossiers

Aktualisierungs-häufigkeit (Jahre)	Gesamteinnahmen aus Gebühren	Große Unternehmen	Mittlere Unternehmen	Kleine Unternehmen	Kleinstunter-nehmen
Aktuell	**€ 10.959.199**	€ 10.126.197	€ 660.287	€ 106.120	€ 66.595
3	**€ 36.530.664**	€ 33.753.991	€ 2.200.956	€ 353.732	€ 221.984
5	**€ 21.918.398**	€ 20.252.395	€ 1.320.574	€ 212.239	€ 133.190
10	**€ 10.959.199**	€ 10.126.197	€ 660.287	€ 106.120	€ 66.595

- **Einführung von Abgaben für Aktualisierungen, die durch Bewertungen der ECHA ausgelöst werden:** Diese Option ist mit den Szenarien zur Erweiterung der Bewertung von Stoffen >1000 t/a verbunden (und nicht mit dem gesetzlich definierten Minium von 5 % der Dossiers). Sie adressiert das Problem, dass die ressourcen- und zeitintensive Arbeit der ECHA bei der Ermittlung von Defiziten in den Registrierungsdossiers, nicht durch die aktuellen Aktualisierungsgebühren finanziert wird. Diese Option konnte aufgrund von Zeit- und Budgetrestriktionen nicht quantifiziert werden, wobei jedoch ein Vorschlag erarbeitet wurde, wie solche Abgaben ausgestaltet werden könnten.

  Es wird vorgeschlagen kein vollständig neues Gebührensystem zu etablieren, sondern die Gebühr als Multiplikator für all diejenigen Situationen zu verwenden, wo eine

Aktualisierung deshalb notwendig wird, weil die ECHA nicht-konforme Informationen in den Registrierungsdossiers identifiziert hat, die zu beheben sind (anders als bei Aktualisierung, die Registranten in Eigeninitiative unternehmen). Hätte dieser Multiplikator z. B den Wert „5“, so wäre die Aktualisierungsgebühr für von der ECHA identifizierte Defizite 5 Mal höher als die Gebühr, welche Registranten zu entrichten hätten, wenn sie aus eigenem Antrieb aktualisieren würden. Ein solcher Multiplikator für durch Dossier-bewertungen ausgelöste Aktualisierungen würde einen Anreiz für Registranten darstellen, welche ihre gesetzlichen Pflichten erfüllen und sicherstellen, dass ihre Dossiers aktuell und mit REACH konform sind und würde Registranten bestrafen, die dies nicht tun.

- **Einführung von Abgaben für einen Zugang zu “erweiterten Datenleistungen”:** ECHA besitzt einen großen Datenpool und ermöglicht den Zugang zu verschiedenen Online-Datenbanken. Als Teil dieser Studie wurde geprüft, ob und wie ECHA für diese Zugänge eine Gebühr erheben könnte, z. B. mittels einer “pay wall”. Diese Option wurde allerdings als problematisch angesehen: Die REACH-Artikel 118 und 119 bestimmen eindeutig, dass jedwede verfügbare Information kostenfrei und online zur Verfügung gestellt werden muss. Außerdem ist die Verfügbarkeit (kostenloser) Information wichtig, um die politischen Ziele von REACH zu erreichen. Daher wurde die Erhebung von Gebühren für „erweiterte Leistungen im Bereich des Datenzugangs“ weder als hilfreich noch als mit den REACH-Zielen und den Pflichten der ECHA konsistent angesehen. Daher wurde diese Option gestrichen und nicht im Detail geprüft.

1 Introduction

1.1 Objectives of the study

The aim of this study is to propose a concept to finance ECHA's activities to implement REACH and CLP in a mid-term perspective (i.e. until app. 2023-2028), which can be introduced into the discussions at EU level. The concept may include elements, which are currently not foreseen in existing legislation.

The specific objectives include the following research questions:

- What will be ECHA's future tasks and the associated expenditure?
- Which income options could contribute to the overall financing of ECHA in the future?
  - For which tasks may ECHA require fees and what could be a possible fee structure?
  - Which role should/could budget contributions from the EU or the Member States play?
  - What other financing options could be developed?
- Can financing models motivate registrants and other actors to use ECHA's resources as efficiently as possible?
- Which financing models and mechanisms are applied in other agencies and which of these have proven successful?
- What buildings blocks could contribute to the financing of ECHA's REACH and CLP activities?

The focus of the study is on ECHA's activities linked to REACH & CLP. ECHA's non-REACH related work will only be considered in relation to concepts that could be used to generate income with regard to REACH.

1.2 Structure of this report

The remainder of this report is organised as follows:

- Section 2: Overview of ECHA's roles and responsibilities
- Section 3: Levels of expenditure and funding of REACH/CLP activities to date
- Section 4: Future scenarios for ECHA's work, expenditure and funding
- Section 5: Alternative scenarios and funding mechanisms

2 Overview of the European Chemicals Agency - ECHA

2.1 ECHA's key roles and responsibilities

The European Chemicals Agency (ECHA) was originally established under Article 75 of the REACH Regulation ((EC) 1907/2006) for *the purposes of managing and in some cases carrying out the technical, scientific and administrative aspects of this [the REACH] Regulation and to ensure consistency at Community level in relation to these aspects*. As such, it officially came into existence when REACH came into force (1 June 2007), becoming officially autonomous from the European Commission on 1 January 2008.

Being established by the REACH Regulation, ECHA's structure and function in relation to REACH is enshrined within that regulation. Title X (comprising Articles 75 to 111 of REACH) sets out the tasks, responsibilities and structure of the Agency in great detail, covering everything from the composition of the agency (boards, committees, forum, etc.) structure and to the tasks and management structure and reporting. Article 77 (provided in Box 2.1) identifies 27 tasks that, in several cases, refer to other Titles and Articles and, in all, 'the Agency' (ECHA) is referred to 457 times in the REACH regulation.

In respect of REACH, as can be seen from Box 1, ECHA's activities and legal duties are many. Its main duties and activities however cover the following overarching activities which themselves are composed of a number of actions and activities to meet the requirements of the legislation:

- ***Substance registration:*** There are many parts to the registration process but ECHA's main activities relate to provision of a system for and guidance on the submission and processing of dossiers for the registration of substances, the assessment, checking and follow up of those dossiers and updates to those dossiers and the making of non-confidential information available to stakeholders and the public in line with the requirements of the legislation;

- ***Dossier and substance evaluation:*** The evaluation of dossiers comprises examination of testing proposals and compliance checking to verify that registration dossiers comply with the information requirements of the REACH Regulation –the legislation requires for a minimum of 5% of the dossiers for each tonnage band to be checked. Substance evaluation involves verifying whether a substance/use suspected of constituting a risk actually poses a risk for human health or the environment. This is carried out by Member States with ECHA playing a coordinating role;

- ***Authorisation and Restriction:*** ECHA updates the Candidate List of substances of very high concern (SVHCs) and prepares recommendations those to be subject to authorisation (through inclusion in Annex XIV to REACH). It provides support to and guidance for companies applying for authorisation, public consultation on those applications as well as supporting Rapporteurs from the Risk Assessment Committee (RAC) and Socio-economic Analysis Committee (SEAC). On Restriction, when requested by the Commission, ECHA must prepare proposals for restrictions either by itself or working together with Member States to prepare the required dossier as well as undertake public consultations and support the RAC and SEAC.

Box 1: Tasks, responsibilities of the ECHA set out in Article 77 of REACH

1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific and technical advice on questions relating to chemicals which fall within its remit and which are referred to it in accordance with the provisions of this Regulation.

2. The Secretariat shall undertake the following tasks:
(a) performing the tasks allotted to it under Title II; including facilitating the efficient registration of imported substances, in a way consistent with the Community's international trading obligations towards third countries;
(b) performing the tasks allotted to it under Title III;
(c) performing the tasks allotted to it under Title VI;
(d) performing the tasks allotted to it under Title VIII;
(e) establishing and maintaining database(s) with information on all registered substances, the classification and labelling inventory and the harmonised classification and labelling list established in accordance with Regulation (EC) No 1272/2008. It shall make the information identified in Article 119(1) and (2) in the database(s) publicly available, free of charge, over the Internet, except where a request made under Article 10(a)(xi) is considered justified. The Agency shall make other information in the databases available on request in accordance with Article 118;
(f) making publicly available information as to which substances are being, and have been evaluated within 90 days of receipt of the information at the Agency, in accordance with Article 119(1);
(g) providing technical and scientific guidance and tools where appropriate for the operation of this Regulation in particular to assist the development of chemical safety reports (in accordance with Article 14, Article 31(1) and Article 37(4)) and application of Article 10(a)(viii), Article 11(3) and Article 19(2) by industry and especially by SMEs; and technical and scientific guidance for the application of Article 7 by producers and importers of articles;
(h) providing technical and scientific guidance on the operation of this Regulation for Member State competent authorities and providing support to the helpdesks established by Member States under Title XIII;
(i) providing guidance to stakeholders including Member State competent authorities on communication to the public of information on the risks and safe use of substances, on their own, in mixtures or in articles;
(j) providing advice and assistance to manufacturers and importers registering a substance in accordance with Article 12(1);
(k) preparing explanatory information on this Regulation for other stakeholders;
(l) at the Commission's request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;
(m) keeping a Manual of Decisions and Opinions based on conclusions from the Member State Committee regarding interpretation and implementation of this Regulation;
(n) notification of decisions taken by the Agency;
(o) provision of formats for submission of information to the Agency.

3. The Committees shall undertake the following tasks:
(a) performing the tasks allotted to them under Titles VI to X;
(b) at the Executive Director's request, providing technical and scientific support for steps to improve cooperation between the Community, its Member States, international organisations and third countries on scientific and technical issues relating to the safety of substances, as well as active participation in technical assistance and capacity building activities on sound management of chemicals in developing countries;
(c) at the Executive Director's request, drawing up an opinion on any other aspects concerning the safety of substances on their own, in mixtures or in articles.

4. The Forum shall undertake the following tasks:
(a) spreading good practice and highlighting problems at Community level;
(b) proposing, coordinating and evaluating harmonised enforcement projects and joint inspections;
(c) coordinating exchange of inspectors;
(d) identifying enforcement strategies, as well as best practice in enforcement;

Box 1: Tasks, responsibilities of the ECHA set out in Article 77 of REACH

(e) developing working methods and tools of use to local inspectors;
(f) developing an electronic information exchange procedure;
(g) liaising with industry, taking particular account of the specific needs of SMEs, and other stakeholders, including relevant international organisations, as necessary;
(h) examining proposals for restrictions with a view to advising on enforceability.

In addition to its tasks and legal duties in respect of REACH, ECHA also has duties and responsibilities in respect of:

- the Classification, labelling and packaging of substances and mixtures (CLP) regulation (1272/2008);
- the Biocides regulation (528/2012); and
- the Prior informed consent (PIC) regulation (649/2012) on the export and import of hazardous chemicals.

The latter two regulations (PIC and Biocides) are outside the scope of this study – which is focussed on activities and funding on REACH and CLP. As with REACH, CLP places legal duties on ECHA. In all there are 64 references to ECHA in the CLP Regulation but the main activities in respect of CLP consist of:

- provision of technical guidance on classification and labelling;
- handling and assessing proposals for harmonised classifications; and
- processing C&L notifications and maintaining the C&L inventory.

ECHA also undertakes other work that is outside the scope of regulation per se. For example, following a delegation agreement between ECHA and the European Commission, it hosts the European Union Observatory for Nanomaterials (EUON) which aims to increase transparency and availability of information on nanomaterials. The Commission and the European legislator have requested that ECHA take on other additional responsibilities in the future. These include the creation of a new database on substances of very high concern under the Waste Framework Directive or the creation of a searchable database for information on mixtures in case of emergency health response. To date, no additional budget is foreseen for these additional responsibilities. These additional activities are out of the scope of this study, which focusses only on expenditure and revenue directly related to REACH/CLP activities.

3 Expenditure and funding of REACH/CLP activities to date

3.1 Expenditure on REACH/CLP Activities

3.1.1 Overview

ECHA's expenditure (and revenue) is reported in both its annual budget reports and accounts. Owing to different accounting rules and procedures, each set of documents (budgets versus accounts) is prepared in a slightly different way and each provides a slightly different breakdown and treatment of figures. However, both sets of documents have been reviewed for all the years 2008 to the present and figures for expenditure and revenue have been collated.

As already noted, ECHA also has responsibilities under PIC and Biocides regulations in addition to those under REACH/CLP. The structure and rules for ECHA's accounts and budgets were altered in 2014 to provide a separation between REACH/CLP and other activities. The budgets and accounts are organised under the following formal titles:

- **Operating expenditure** – the cost of operational activities and time spent broken down by task under the relevant legislation; and
- **Staff and buildings** – the costs of assets and other overheads associated with the organisation as a whole. To the extent possible, this is apportioned to the different legislative activities where, as noted above, from 2014, separate apportioning between REACH/CLP and PIC/Biocides was introduced.

The sub-sections below provide historical data on each of these titles and the total cost as background to the consideration of future costs and funding requirements.

3.1.2 REACH/CLP operating expenditure

Figure 1 provides a breakdown of REACH/CLP operating expenditure from the Budget reports covering the period 2010 to 2018 (with data for 2018 drawn from the projections in the most recent programming document (2018-2020[9]). Operating expenditure is broken down into the following categories of work which is defined in the Budget Reports as follows:

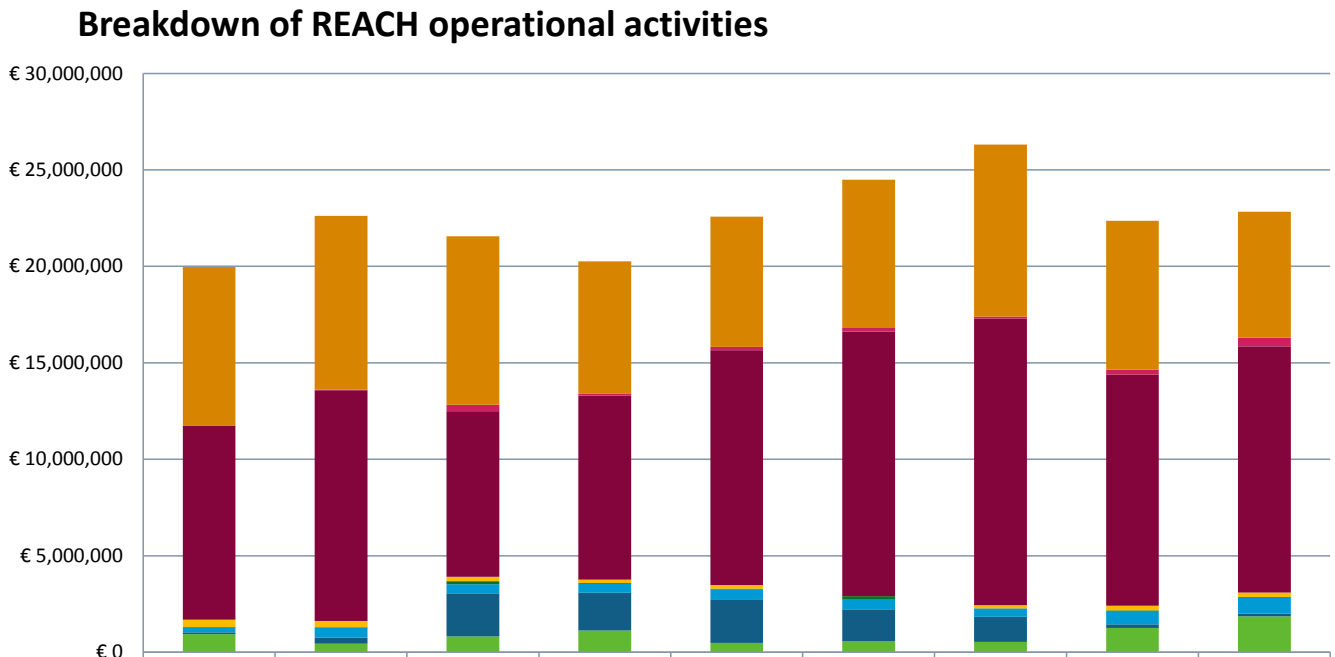
- **Registration, data-sharing and dissemination:** the cost of registration, data sharing & dissemination activities, and in particular clarifying substance identity and use of (Quantitative) Structure Activity Relationship ((Q)SAR) models, invoicing, verification of completeness checks, setting conditions on process orientated research and development notifications (PPORDs), inquiry, pre-registration, assessment of confidentiality claims, dissemination of substance information, providing support to industry in the preparation of their dossiers, and responding to helpdesk questions. In particular it will cover costs of meetings, consultancy, experts, studies and other costs related to the activity;
- **Evaluation:** the cost of dossiers evaluation including interfaces with other REACH processes, interfaces between dossiers and substance evaluations, providing advice to Member States on their role in the evaluation processes and support the industry in

[9] https://echa.europa.eu/documents/10162/22837330/spd_2018-2020_mb_48_2017_mr_en.pdf

improving the quality of the registration dossiers. In particular it will cover costs of meetings, consultancy, experts, studies and other costs related to the activity;

- **Risk Management:** the costs of processing and further development of the procedures of authorisations and restrictions. It covers the costs of revising the candidate list of substances of very high concern (SVHC) and recommending SVHC to be included in Annex XIV "authorisation list", preparation (on request by the Commission) of Annex XV dossiers for SVHCs or restrictions, providing advice to Member States on preparing Annex XV dossiers for SVHC or for restrictions and on processing comments received in public consultations, providing support to increase knowledge of the practical application of socio-economic assessment, providing further guidance on selecting the best risk management options for SVHCs and other substances and supporting the industry to ensure good understanding of their obligation towards authorisation and restrictions. In particular it will cover costs of meetings, consultancy, experts, studies, training events, and other costs related to the activity;
- **Classification and labelling:** the cost of tasks performed for the activity of classification and labelling. These tasks include providing support to MSCAs and guidance to industry on issues not dealt within the current guidance, finalisation of the revision of the guidance on proposals for harmonised C&L, new practical guidance on preparing and submitting notifications to the C&L inventory, costs of an awareness campaign to inform industry about the CLP Regulation and the costs of handling requests for the use of alternative names. The appropriations cover also the costs related to the Poison Centres. In particular it will cover costs of meetings, consultancy, experts, studies and other costs related to the activity;
- **Advice and assistance through guidance and helpdesk:** the costs of providing advice and support through guidance to authorities, industry and other audiences. It also covers the costs of the network of the national helpdesks, its tools and any other costs related to the activity. In particular it will cover costs of meetings (including reimbursements and catering), consultancy, experts, studies, IT tools and other costs related to the activity;
- **Scientific IT tools:** all of the costs of acquiring, developing and maintaining scientific IT tools such as REACH-IT (including the Business Continuity system), IUCLID, CHESAR, CASPER, RIPE, ODYSSEY, Dissemination website, etc. In particular it will cover costs of meetings, consultancy, experts, studies, purchase of services, purchase or development of IT software, hardware and their maintenance and other costs related to the activity;
- **Scientific and technical advice to EU institutions and bodies:** all costs of scientific and technical advice to Member States, EU institutions and bodies. In particular it will cover costs of meetings, consultancy, experts, studies and other costs related to the activity; and
- **Other Cross cutting and horizontal activities:** ECHA committees and forum, board of appeal, communications including translations, international cooperation, missions, external training, cooperation with international organisations (such as OECD) for IT programmes.

Figure F: Overview of ECHA's operating expenditure



	2010	2011	2012	2013	2014	2015	2016	2017	2018
Other operational activities cross cutting, international, horizontal and multi-annual reporting activities	€ 8,223,202	€ 9,007,427	€ 8,734,366	€ 6,858,754	€ 6,750,240	€ 7,693,663	€ 8,912,339	€ 7,703,336	€ 6,518,624
Scientific and technical advice to EU institutions and bodies		€ 25,023	€ 330,500	€ 103,500	€ 171,450	€ 188,689	€ 103,371	€ 259,000	€ 446,206
Scientific IT tools	€ 10,044,009	€ 11,954,079	€ 8,579,450	€ 9,536,800	€ 12,178,915	€ 13,704,528	€ 14,854,250	€ 11,978,562	€ 12,763,786
Advice and assistance through guidance and helpdesk	€ 387,683	€ 329,169	€ 234,360	€ 167,300	€ 180,885	€ 0	€ 161,401	€ 250,900	€ 224,100
Classification and labelling	€ 50,150	€ 20,058	€ 162,500	€ 36,200	€ 51,000	€ 154,965	€ 13,194	€ 64,218	€ 48,285
Risk Management	€ 226,300	€ 514,675	€ 462,500	€ 470,300	€ 501,810	€ 536,198	€ 435,522	€ 650,905	€ 822,656
Evaluation	€ 95,001	€ 325,198	€ 2,239,950	€ 1,952,500	€ 2,261,140	€ 1,654,669	€ 1,295,374	€ 195,273	€ 136,000
Registration, datasharing and dissemination	€ 932,879	€ 437,089	€ 815,000	€ 1,131,000	€ 485,960	€ 562,988	€ 533,989	€ 1,254,168	€ 1,865,491

Source: ECHA budget reports. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

As can be seen from the data in Figure 1, some of the costs of the different activities vary significantly from year to year and others do not/do less so. A significant cause of the variation is likely to be registration deadlines. Registration deadlines in 2010,2013 and 2018 affect different costs in different ways and may require more intensive activity in the years running up to/the deadline year (for example, expenditure on registration, data-sharing, etc.) or in the years following (for example, evaluation of received dossiers). The intensive work periods for some components are also likely to impact on others by virtue of staff effort being shifted from one activity to another and back. In general the following describes each cost component:

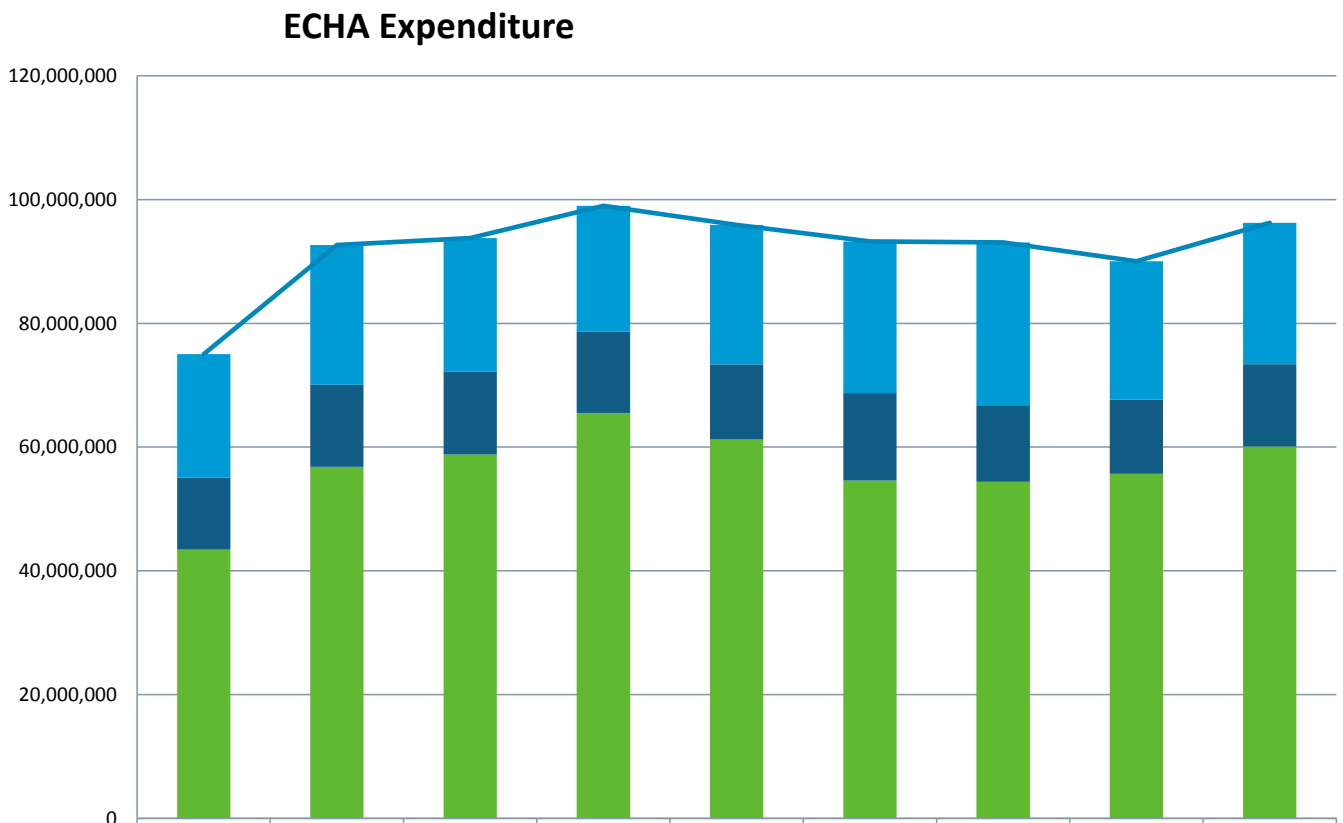
- Registration, data-sharing and dissemination: Increases in the run-up to and year of a registration deadline and then falls back to a lower level;
- Evaluation: Varies – again probably related to registration deadlines and compliance checking/evaluation of dossiers as well as substances;
- Risk Management: Has increased over time as SVHC's identified for inclusion in Authorisation and Restriction lists
- Classification and labelling: again varies with expenditure perhaps higher in 2012, the year before the 2013 REACH registration deadline. This is perhaps owing to the need to issue guidance on the classification of substances based on new information but could also be because 2012 marked the beginning of the public Classification and Labelling Inventory (CLI). The increase in costs in 2015 may correlate with the application of CLP to mixtures from that year for which guidance would have been needed to be produced
- Advice and assistance through guidance and helpdesk: Variable with some suggestion that increases to a peak in a registration deadline year
- Scientific IT tools: This is 'single' most significant item of expenditure. Geared towards ensuring that the tools necessary to enable data analysis submission of dossiers, this item expenditure remains consistently high, typically around the €10million per year mark but experiencing an increase of €2-4 million in the run-up to the 2018 registration deadline probably due to efforts to increase usability for SMEs amongst other things;
- Scientific and technical advice to EU institutions and bodies: Again varies somewhat with the approach of a registration deadline, waning in-between; and
- Other Cross cutting and horizontal activities: a relatively constant but significant background of activity and expenditure.

3.1.3 Total expenditure including staff and buildings

The operating expenditure provided in Figure 1 provides only a part of the overall picture on ECHA's expenditure and to these must be added the expenditure under the titles staff and buildings. As noted in above, separate entries are provided in the Annual Budgets for expenditure on staff and buildings with accounts/budgets assuming that 90% of the expenditure is attributable to REACH/CLP activities as opposed to PIC and Biocides activities. Figure 2 provides data staff and building costs for REACH/CLP from the Annual Budgets together with the total REACH operating expenditure (from Section 3.1.2) and the resulting total combined expenditure. Note again that it is only from 2014 onwards that a formal separation was made in accounts between REACH/CLP activities and those under PIC/Biocides but, at the same time, work on these activities would have only started a year or two before this time.

Considering this, the data suggests that data, operational expenditure makes up around 25% of total annual expenditure which appears to be around the €94-95 million per year mark.

Figure G ECHA's total REACH/CLP expenditure



	2010	2011	2012	2013	2014	2015	2016	2017	2018
REACH operating expenditure	19,959,224	22,612,718	21,558,626	20,256,354	22,581,400	24,495,700	26,309,440	22,356,362	22,825,148
Building, equipment and miscellaneous operating expenditure	11,624,281	13,220,000	13,397,100	13,170,600	12,100,320	14,101,605	12,347,132	11,983,639	13,285,047
Staff	43,426,635	56,824,782	58,811,180	65,537,300	61,234,020	54,618,876	54,412,542	55,683,201	60,121,356
Total	75,010,140	92,657,500	93,766,906	98,964,254	95,915,740	93,216,181	93,069,114	90,023,201	96,231,551

Source: ECHA budget reports. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

3.2 Funding for ECHA's work on REACH/CLP activities

3.2.1 Current funding mechanisms for ECHA's REACH/CLP Activities

ECHA's activities in relation to both REACH and CLP are funded by a combination of revenue from fees and charges balanced with an EU subsidy and contributions from Member States and EFTA.

The nature of fees for registration, authorisation and appeals under REACH are defined in Article 74 of the REACH Regulation and the levels are set out in the Fee Regulation ((EC) 340/2008 as modified by (EC) 2015/864). Similarly, CLP fees are defined in the CLP Regulation and the levels are set in the CLP fee regulation ((EC) 440/2010).

Fees and charges for each of the core elements (registration, authorisation, etc.) of REACH and CLP can be broken down into the following:

- **Registration of substances**:
  - Registration of Phase-in and non-phase in (new) substances– fees for which are set out in the REACH fee regulation and are differentiated by type of registration (full or intermediate), tonnage band and by size of enterprise as well as whether the submission is joint or individual;
  - Updates to registration dossiers – for which there are several kinds of update (from changes in identity of the registrant through to changes in tonnage band or availability of new studies) each demanding a different fee and each being differentiated by size of company and, in relation to changes in tonnage band, the scale of change of tonnage band;
  - Notifications of substances subject to product and process orientated research and development (PPORD) and extensions to existing or new PPORD notifications – fees for which are differentiated by size of enterprise;
- **Authorisation of substances identified and added to Annex XIV** - sub-divided into:
  - Applications for Authorisation – fees for which are comprised of a base fee plus additional fee(s) depending on the number of additional substances, number of uses and number of applicants with all of these being differentiated by size of enterprise;
  - Charges for the review/renewal of an authorisation – which appear identical to the above but would be incurred at a future point in time for some substances, their uses and applicants;
- **Appeals against Agency decisions** - in respect of Article 9 (PPORD), or 20 (dossier completeness check), 27 (sharing of information), 30 (testing and sharing of information), 51 (dossier evaluation decisions) or 52 (substance evaluation decisions) – different fees apply to different Articles and these are differentiated by size of enterprise.

In addition to the fees above, Articles 11 and 13(4) of the REACH fee Regulation ((EC) 340/2008) also allow fees and charges to be levied for services other than those listed in Article 74 of REACH.

Article 11 of the REACH fee Regulation ((EC) 340/2008) allows ECHA to levy fees and charges for services other than those listed in Article 74 of REACH. Here, Article 11 allows that a *charge may be levied for administrative and technical services provided by the Agency at the request of a party which are not covered by another fee or charge provided for in this Regulation. The level of the charge shall take into account the workload involved*. The regulation adds the caveat that charges cannot be levied for assistance provided by the Helpdesk or for the support to Member States provided for in Article 77(2)(h) and (i)[10] but, clearly, within the context of this study, there is scope to consider charges for other services.

The mechanism by which services and charges under Article 11 are drawn up is established under Article 11(5) of the REACH fee regulation. This makes the Management Board of the Agency responsible for drawing up the charges/fees which can be adopted once a favourable opinion has been given by the Commission. The current services and charges are set out in the Management Board decisions of 12 November 2010[11]. From this, only one service and charge is in operation under the provisions of Article 11 of the REACH Fee regulation and this relates to *where it [ECHA], on request by a party submitting a dossier under Regulation (EC) No 1907/2006 [REACH], provides a service that is not foreseen in Regulation (EC) No 1907/2006 [REACH} and that facilitates the submission of the dossier*. The daily rate set for calculation of these service charges is €600 per day.

Article 13(4) of the REACH fee Regulation provides the specific capacity for ECHA to levy a charge on anyone identified as falsely/erroneously claiming a fee reduction or fee waiver (to be added to the correct fee liable). The charges for this are also set out in the Management Board decisions of 12 November 2010[11]. However, as reported in the Commission recent staff working document[12] reviewing the performance of REACH, an appeal to the EU General Court[13] found that the level of the charge was disproportionate with regard to the savings derived from the false declaration as SME and, following that judgement, ECHA revised the administrative charge for the SME verification by capping it to a maximum of 2.5 times the financial gain derived from the false declaration on the size status[14].

[10] 77(2)(h) - providing technical and scientific guidance on the operation of this Regulation for Member State competent authorities and providing support to the helpdesks established by Member States under Title XIII; (i) providing guidance to stakeholders including Member State competent authorities on communication to the public of information on the risks and safe use of substances, on their own, in mixtures or in articles.

[11] Decision amending Decision MB/D/29/2010, as amended by Decision MB/21/2012, on the classification of services for which charges are levied (Management Board Decision 14/2015- see https://echa.europa.eu/documents/10162/13608/mb_decision_14_2015_en.pdf/5cb1ec81-2e3a-419b-9ff0-4c2c5e4d527c

[12] SWD accompanying the document Communication from the Commission to the European Parliament, the Council and the European Social and Economic Committee Commission General Report on the operation of REACH and review of certain elements Conclusions and Actions, SWD/2018/058 final - https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD%3A2018%3A58%3AFIN

[13] Judgement of the General Court of 2.10.2014 in the case T-177/12 Spraylat GmbH v European Chemicals Agency (ECHA)

[14] ECHA Management Board Decision 14/2015 of 4 June 2015

In terms of fees charged for ECHA operations on CLP the following aspects are chargeable:

- a request to use of an alternative chemical name according to Article 24(1) of CLP with an initial fee covering a substance in up to five mixtures and a supplementary fee has to be paid for every ten additional mixtures. Fees are differentiated by size of enterprise; and
- Submission of a proposal for harmonised classification and labelling of a substance according to Article 37(3) of CLP for which fees are also differentiated by size of enterprise.

Reduced fees for SMEs

As is outlined above, fees for REACH and CLP are differentiated by size of company to ensure that smaller companies (with smaller turnover) are not affected disproportionately relative to large companies. The existing definition of an SME is set out in Commission Recommendation 2003/361/EC. However, the need to alter this definition is currently being assessed by the Commission. This is partly owing to the need to update aspects such as the turnover thresholds used to define SMEs but also other aspects of which the most significant is the potential for groups of enterprises whose real economic power exceeds that of genuine SMEs to claim SME status for the purpose of reduced fees under REACH and CLP in particular. Here, for example, on 15 September 2016 the European Court of Justice ruled on two cases against administrative decisions of ECHA concerning claims for SME status where there was a question mark over the independence of the enterprises. This brought it to the attention of the Commission that the current definition is not clear and can lead to:

- the granting the status of SMEs to groups of enterprises whose real economic power exceeds that of genuine SMEs;
- an artificial increase in the number of enterprises considered as SMEs despite their not being SMEs within the spirit of the Recommendation;
- large companies designing corporate structures (such as intermediate, 'empty-shell' special purpose companies) to benefit unfairly from the support offered to SMEs.

The consultation on revisions was completed between 6 February and 8 May 2018 and the Commission is now considering adoption of appropriate revisions to the SME definition.

3.2.2 Revenue from fees and EU budget contributions to date

Figure 3 provides data on balance of contributions between fees and EU budget contributions from 2008 to 2018.

Fee income is recorded in a slightly different way in the accounts compared with the budgets: The accounts documents record the actual fee income received and the budget reports record the fee income budgeted for that year. As can be seen from the accounts documentation, fee income from the 2010 registration deadline (for substances manufactured or imported in quantities of >1000t) was around €356 million, providing a substantial injection of revenue. This 2010 fee income, combined with receipts for the 2013 registration deadline (for 100-1000t

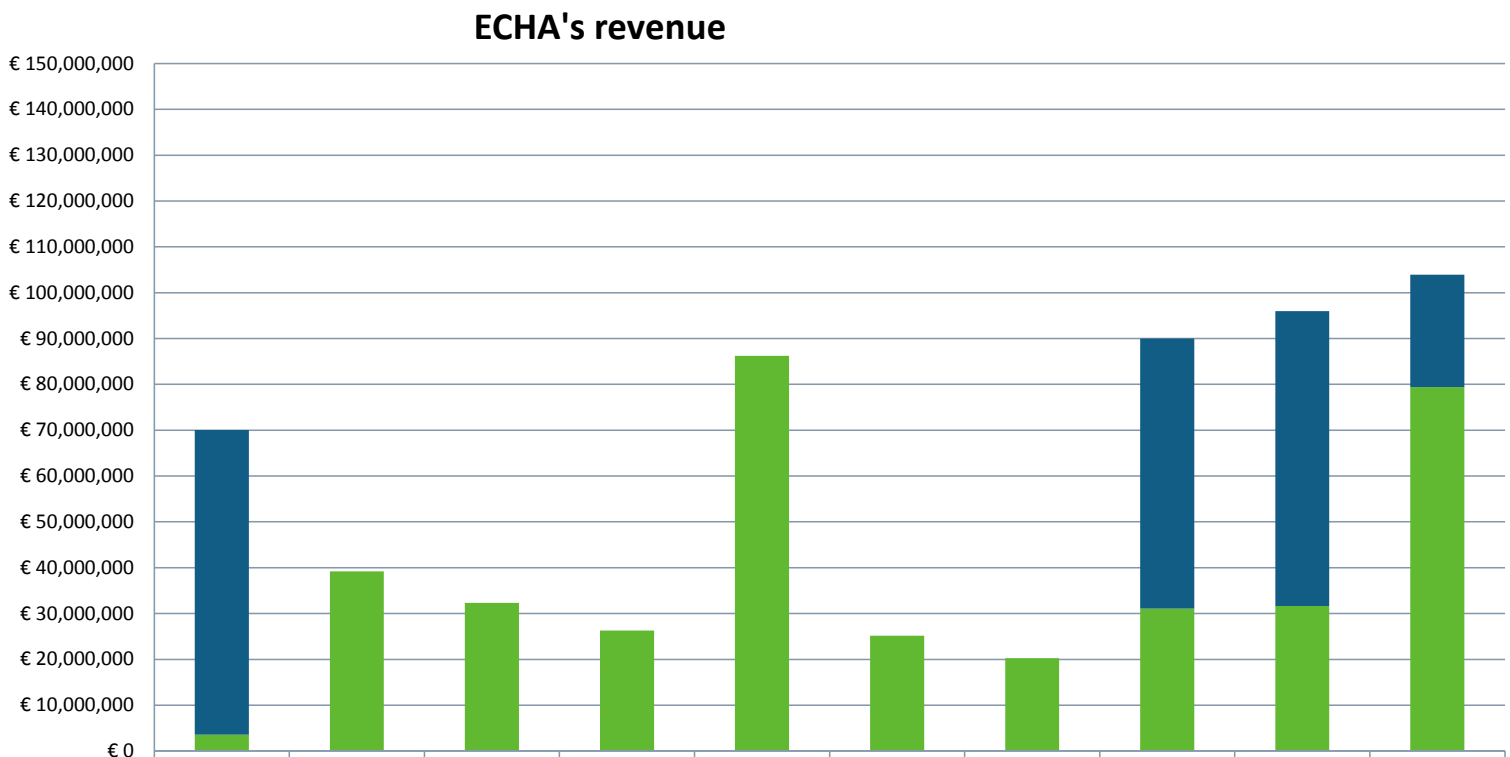
substances) sustained the Agency for the years 2010[15] to 2015 inclusive and no balancing contribution was required from the EU budget until 2016.

From 2011 onwards, figures given on fee income in the budget reports and the accounts are broadly in agreement. The only departure between the two relates to the aforementioned large fee income from 2010 which was used to provide a new Title in the budget reports (Title 199) under the heading 'balancing fee income' – in effect recording fee income banked for future years.

In all, for the years 2009-2016 total fee income was of the order of €584 million and EU budget contributions were of the order of €120 million which, combined with additional contributions from EEA and individual Member States, covered a total expenditure of around €730 million (excluding direct expenditure in relation to Biocides and PIC).

[15] The balancing contribution from the EU budget for 2010 was refunded to the Commission in 2011 and the figures on EU budget contribution in the figure have been adjusted accordingly.

Figure H: ECHA's revenue from the accounts and budget reports



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
EU Budget contribution (Budget Reports)	€ 66,451,588	€ 0	€ 0	€ 0	€ 0	€ 0	€ 0	€ 58,936,000	€ 64,289,500	€ 24,517,000
Fees (Budget reports)	€ 3,593,000	€ 39,206,700	€ 32,310,000	€ 26,298,000	€ 86,244,640	€ 25,139,004	€ 20,257,069	€ 31,080,259	€ 31,664,289	€ 79,403,406
Fees (Accounts)	€ 2,573,845	€ 355,771,95	€ 30,028,024	€ 25,750,731	€ 86,173,896	€ 24,503,123	€ 25,304,723	€ 34,373,690		
Contributions (inc. from EU Budget) - (Budget Reports)	€ 68,042,588	€ 945,977	€ 2,650,000	€ 1,930,676	€ 3,539,324	€ 1,750,000	€ 1,009,967	€ 60,567,214	€ 65,877,450	€ 24,984,412

Source: ECHA budget reports and accounts. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

According to these data, then, for the 2009-2016 period, fees and charges under REACH/CLP have covered around 80% of total expenditure. This situation is likely to change now that the last tranche of phase-in substances to be registered under REACH has passed and no future substantial revenue contribution from registration fees can be expected.

Figure 4 provides a breakdown of revenue from fees and charges from registration versus other fees and charges for the period 2011-2018[16] - with the figures for 2018, as mentioned for Figure 3 above, reflecting the best estimate in the 2018-2020 planning document and interpolated fee income post-registration 2018.

As can be seen from these data, fees from registration have, to date, been by far the largest source of revenue from fees and charges and the same applies for the 2010 data, the €355 million registration fees from which sustained the Agency for following six years. The passing of the final 2018 registration deadline largely ends the significant revenue stream seen from registration. The €77million income from Registration 2018 is sufficient only to fund ECHA's activities for 2018 and not successive years in the way that was the case with fee income from Registration 2010.

In terms of the levels of revenue from fees other than registration, this has historically been quite small. Reflecting the time lag between REACH entering into force and the identification of Substances of Very High Concern (SVHCs) for inclusion on Annex XIV (the Authorisation list), fee income from Authorisation was at first small but has increased slightly over time as the 2013 SVHC Roadmap has been implemented. Fee income in 2016 was relatively large, with this being associated with 77 applications from 132 applicants for 112 uses where these mostly related to applications for the use of chromates and, in 2017, fee income dropped back to around level seen in previous years. As such, the income from 2016 represents a spike in the data associated with authorisation of a 'substance' (chromates) with a large number of uses and this is not indicative of an ongoing future pattern of increases in fees from Authorisation over time.

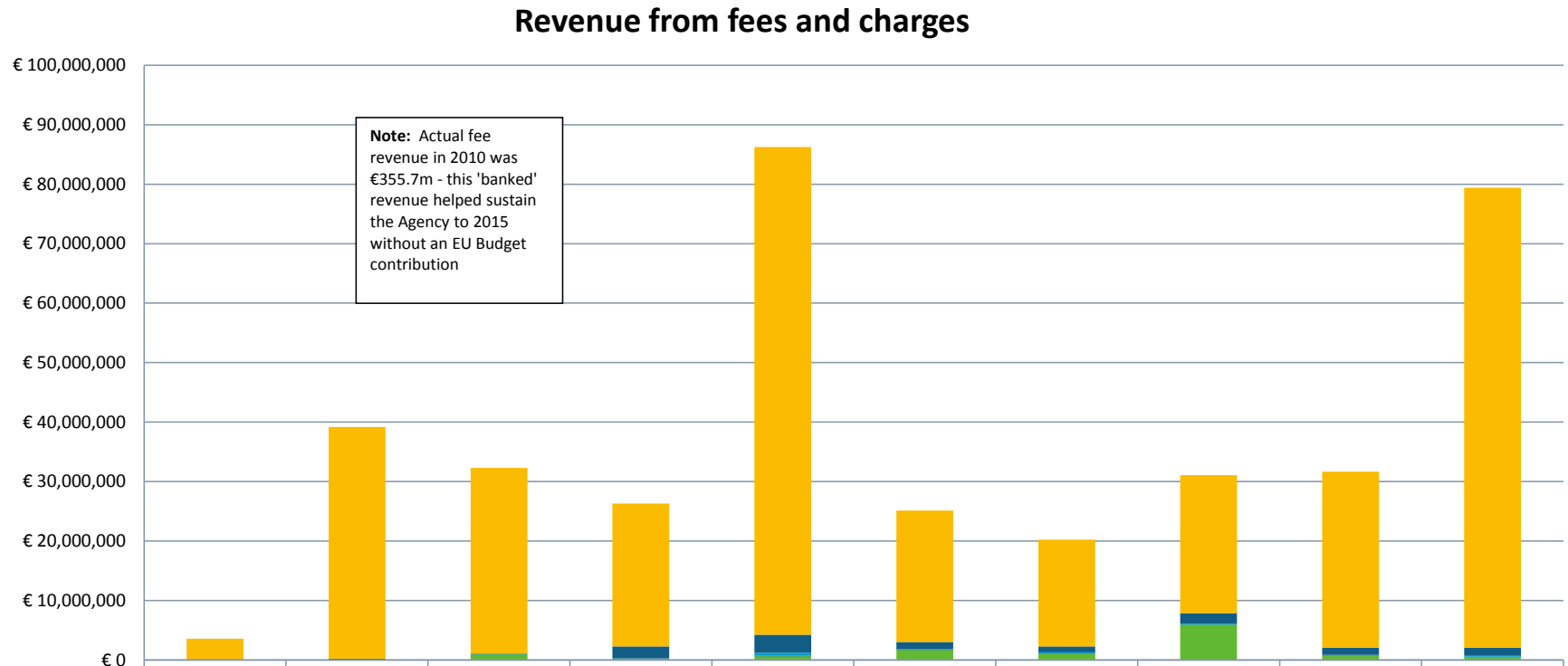
Income from appeals is low and fairly constant, as is that from CLP, albeit being slightly higher. The fee income associated with the category recorded as 'other fees and charges' has, at times, been more significant in value. 'Other fees and charges' are associated with:

- Charges under Article 13(4) of the fee regulation in relation to the making of false/erroneous claims for a fee reduction or fee waiver; and
- Charges under Article 11 of the fee regulation in relation to unforeseen assistance with the submission of a dossier.

In both cases these fees/charges are closely linked to preparation and submission of dossiers for Registration and the associated differentiated fees for SMEs. This relationship can be clearly seen in the data in Figure 4 which shows a peak in 'other fees and charges' corresponding with the 2013 registration deadline. As already noted, with the passing of the 2018 registration deadline, fees from registration will cease to provide a significant revenue stream and, similarly, revenue from these 'other fees and charges' is also likely to tail off.

[16] 2010 has been omitted owing to the previously discussed issue of differences in the recording of the anomalously large fee income for that year in accounts versus budget reports (from which these data are taken).

Figure I: Breakdown of fee revenue



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Registration	€ 3,473,000	€ 38,976,700	€ 31,200,000	€ 24,000,000	€ 82,000,000	€ 22,077,004	€ 17,955,000	€ 23,210,566	€ 29,553,000	€ 77,308,000
Other fees and charges	€ 0	€ 0	€ 0	€ 2,000,000	€ 3,000,000	€ 1,200,000	€ 1,000,000	€ 1,750,000	€ 1,233,700	€ 1,357,000
CLP	€ 0	€ 0	€ 80,000	€ 68,000	€ 510,000	€ 100,000	€ 229,000	€ 144,000	€ 148,613	€ 148,000
Appeals	€ 120,000	€ 230,000	€ 130,000	€ 50,000	€ 134,640	€ 80,000	€ 7,069	€ 14,244	€ 14,315	
Authorisation	€ 0	€ 0	€ 900,000	€ 180,000	€ 600,000	€ 1,682,000	€ 1,066,000	€ 5,961,449	€ 714,661	€ 570,077

Source: ECHA budget reports and accounts. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

In summary, then, whilst some registrations will still be submitted post-2018 for non-phase in (i.e. new) substances, late registrations for phase-in substances and updates to registration dossiers (for example owing to change in tonnage band) these will be much fewer in number than in the past and so far less revenue will be generated from the category of Registration in the future. Revenue from other sources such as authorisation, appeals, and other is also likely continue to be modest. As such, without intervention, the main source of revenue to fund ECHA's activities will be EU budget balancing contributions.

The rest of the report considers likely expenditure and funding needs in the short, medium and long-term, the contribution that existing fee mechanisms will make to covering these funding needs and the extent to which EU budget contributions will need to cover any shortfall. The report then considers what alternative funding mechanisms could be put in place to both to reduce the burden on the EU budget and, potentially, to promote REACH objectives.

4 Future scenarios for ECHA's expenditure and revenue

4.1 Developing a baseline future scenario

The original 2006 expectation was that post registration 2018 ECHA would be able to progress through completeness checks, substance evaluation, identification and authorisation SVHCs and restrictions etc., with a slowly diminishing list of tasks and substances. The reality, however, seems to be not as anticipated in 2006. For example, the Commission's REACH Review[17] identified that "*progress towards the objectives is lagging behind initial expectations*" and that non-compliance of registration dossiers was one of (the four) issues requiring most urgent action. In light of such conclusions, ECHA's draft Strategic Plan 2019-2023[18] identifies that:

> *The European Commission's REACH Refit Evaluation[19] concludes that REACH is effective, but not yet efficient and that the implementation of REACH is lagging behind the original expectations in meeting its political objectives. Indeed, there are gaps and severe shortcomings in data provided by industry through REACH registration dossiers, especially with regards to long-term effects of their substances on human health and the environment and in relation to the uses and exposure*

and that:

> *This means that, on the one hand, ECHA's, Member States' and European Commission's activities implementing REACH and CLP will need, on all fronts, to be intensified in order to meet the political objectives set in the legislation and, on the other hand, that the evaluation activity (including examination of testing proposals and compliance checks) will need to continue at high intensity longer than originally planned. Hence, rather than decreasing during the next Multi-annual Financial Framework, it will need to continue at the current intensity.*

This would imply a continuing operational expenditure at current levels (around €100million) for the next four years (at least) if the political objectives of REACH and CLP are to be met, as anticipated. In addition, the Commission and the European legislator have requested that ECHA take over additional responsibilities in the future. These include the creation of a new database on substances of very high concern under the Waste Framework Directive and the creation of a searchable database for information on mixtures in case of emergency health response. To date, no additional budget is foreseen for these additional responsibilities. These additional responsibilities have not been assessed explicitly in this study but their existence (without additional funding) will tend to put further pressure on ECHA's resources and further increase the need to secure supplementary sources of funding.

In addition to changes to ECHA's anticipated work load, other changes have been made that affect the revenue side of the equation. REACH Commission Implementing Regulation (EU) 2018/895 has revised the fees for applications for authorisation of SVHCs, amending the fees set out in the Regulation (EC) No 340/2008 so that they take better account of the amount of work involved in assessing applications.

[17] https://ec.europa.eu/growth/sectors/chemicals/reach/review_en
[18] Expected to be adopted in December 2018.
[19] https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

In order to estimate ECHA's future expenditure and revenue we have sought to develop a baseline scenario for ECHA's future work over the following time periods:

- Short term - 4 years from present
- Mid-term – 10 years from present
- Longer-term - 15-20 years from present.

Projections have been made on the basis of available information including complete registration data that has been kindly supplied by ECHA. This has been used to calculate costs of different elements in relation to, for example, numbers of dossiers in the registration database on the basis of work undertaken so far and associated effort per unit of work.

Clearly, the further into the future one seeks to project, the more uncertain will be the estimates but the starting point has been a baseline scenario for REACH/CLP activities reflecting the assumptions that:

- The vast majority of phase-in substances are registered. As with previous deadlines there will be some late registrations and a similar late submission rate will apply as previous deadlines;
- Updates of dossiers is around 10% per year[20];
- The rate of new substance registration remains at current levels;
- The annual number of substances for authorisation continues at current rates taking average numbers of uses applied for/applicants based on experience with Authorisation to date and adjusted for the new fees established in (EU)2018/895;
- Work in the short-term proceeds as per ECHA's draft Strategic Plan 2019-2023 which, as noted above identifies that "evaluation activity (including examination of testing proposals and compliance checks) will need to continue at high intensity longer than originally planned";
- REACH work in the medium-term reduces as evaluation meets the minimum target of 5% of dossiers in each tonnage band but continues at a lower background level (@20% of annual costs of shorter term) into the medium term;
- REACH work in the longer term reflects continuing registration of new substances combined with updates, other ongoing tasks including maintenance of IT and databases, international co-operation and scientific advice and continuing evaluation.

4.2 Estimation of revenue and expenditure for REACH/CLP operational activities

Just as estimates of expenditure on each element have been estimated, so the same assumptions and variables have been applied to generate estimates of revenue from fees.

[20] Analysis of registration data for substances with a declared deadline of 2010 and 2013 for this study suggests an average annual update rate of 7% and 8% respectively. This might be expected to increase slightly as the workload on first registration has now diminished since completion of the 2018 registration deadline.

Estimates for 2019 for each category of fee revenue and expenditure for the baseline scenario are provided in Tables 1 and 2 respectively. These provide a brief description of how the estimate has been derived and how adjustments are made to capture changes in the short, medium and long term. In addition to the baseline scenario two alternative scenarios have also been developed to calculate the expenditure (and fees) associated with the following changes in dossier evaluation:

- Evaluation expanded to all >1000t substances using current screening strategy (as well as that under the baseline); and
- Evaluation expanded to all >1000t substances using higher levels of scrutiny (as well as that under the baseline).

The first of the alternative scenarios assume that the current strategy of focussing on higher tier human health and environmental information and key sections of the dossiers is applied. The second assumes that more comprehensive checks are made requiring four times the current effort per dossier. As both scenarios are likely to result in an increase in the number of updates, income from fees for updating dossiers have been increased to reflect 40% of dossiers being updated under the current strategy and 60% under higher scrutiny.

Table 1: Summary of estimates used to calculate fee revenue

Assumptions	Study predictions for 2019	Annual decline in activity – short-term (4 years)	Annual decline in activity – medium term (10 years)	Annual decline in activity – long term (15-20 years)
New substance registration fees (based on average 2012 onwards)	€ 2,337,000	0%	0%	0%
Update Fees (based on historical rates and statistics on types of update)	€ 10,959,000	0%	5%	10%
Late registration fees (based on % late registrations after 2010/2013)	€ 14,950,000	20%	40%	100%
Authorisation fees (based on average rate of substances for authorisation and uses per substance)	€ 867,000	0%	5%	25%
Appeals fees (calculated as a % of registration fees based on historical data)	€ 107,000	Adjusted in line with registration related fees	Adjusted in line with registration related fees	Adjusted in line with registration related fees
CLP fees (based on typical historical fees for non-deadline years)	€ 147,000	0%	5%	15%
Other fees and charges (calculated as a % of registration fees based on historical data)	€ 1,481,000	Adjusted in line with registration related fees	Adjusted in line with registration related fees	Adjusted in line with registration related fees

For each of the alternative scenarios the following two sub-scenarios have been calculated based on variations in both timescale and the dossiers that are selected:

- evaluation is expanded to all >1000t dossiers (lead, member and individual submissions) over a 20 year period; and
- evaluation is expanded to >1000t dossiers from lead and individual registrants only over a 10 year period.

These timescales and dossier coverage have been selected to keep the options within the bounds of feasibility. Here, if evaluation is expanded to all >1000t dossiers (lead, member and individual submissions) the total number of dossiers that would need to be checked is around 18,760 (accounting for the 5% already checked). Over a 20 year period this equates to around 938 per year. This is around three times the current rate and (just) within the bounds of

possibility. However, reducing the timescale to 10 years would require 1,876 per year on top of the existing evaluations required on substances registered in 2018. This seems an unreasonably high rate of evaluation.

As such, we have considered the alternative option of undertaking evaluations only on lead and individual dossiers (i.e. not member dossiers). This reduces the total number of dossiers to around 2,430 but would still entail evaluation of all of substances and data in dossiers (as any data failings in a lead dossier would also be present in member dossiers which would also need to be updated). Reviewing 2,430 dossiers over 10 years would entail 243 dossiers per year which is well within the bounds of feasibility.

Table 2: Summary of estimates used to calculate workload and expenditure

Assumptions	Study predictions for 2019	Annual decline in activity – short-term (4 years)	Annual decline in activity – medium term (10 years)	Annual decline in activity – long term (15-20 years)
Registration, datasharing and dissemination (calculated as a % of registration fees based on historical data)	€ 500,000	Adjusted in line with registration related fees	Adjusted in line with registration related fees	Adjusted in line with registration related fees
Authorisation expenditure (based on historical data)	€ 651,000	0%	5%	25%
Classification and labelling (calculated as a % of CLP fees based on historical data)	€ 68,000	Adjusted in line with CLP fees	Adjusted in line with CLP fees	Adjusted in line with CLP fees
Advice and assistance through guidance and helpdesk (based on typical historical expenditure in non-deadline years)	€ 200,000	0%	5%	0%
Scientific IT tool (based on typical historical expenditure in non-deadline and preceding years)	€ 10,000,000	0%	0%	0%
Scientific and technical advice to EU institutions and bodies (based on typical historical expenditure in non-deadline years)	€ 200,000	0%	0%	0%
Other operational activities cross cutting, international, horizontal and multi-annual reporting activities (based on typical historical expenditure in non-deadline years)	€ 7,500,000	0%	0%	0%
Evaluation expenditure:				
Evaluation using current screening strategy (5% of 1-100t only)	€ 1,923,000	0%	20% of short-term	20% of short-term
Evaluation expanded to all >1000t substances using current screening strategy (staff costs are also increased to cover expansion in activity) - All registration dossiers (lead, member and individual) over 20 years	€ 6,144,000	0%	0%	0%

Assumptions	Study predictions for 2019	Annual decline in activity – short-term (4 years)	Annual decline in activity – medium term (10 years)	Annual decline in activity – long term (15-20 years)
Evaluation expanded to all >1000t substances using current screening strategy (staff costs are also increased to cover expansion in activity) - Lead and individual registration dossiers only over 10 years	€ 3,017,000	0%	0%	0%
Evaluation expanded to all >1000 using higher scrutiny (staff costs are also increased to cover expansion in activity) - All registration dossiers (lead, member and individual) over 20 years	€ 18,807,000	0%	0%	No activity on >1000t
Evaluation expanded to all >1000 using higher scrutiny (staff costs are also increased to cover expansion in activity) - Lead and individual registration dossiers only over 10 years	€ 6,297,000	0%	0%	No activity on >1000t

4.3 Estimation of staff and building costs

As described in Section 3.3, REACH/CLP operational costs represent only around 25% of total expenditure once staff and building costs are factored in. To capture these in the analysis the expenditure on staff has been linked to REACH operational costs by applying an average Euro unit of expenditure on staff per Euro unit expenditure on REACH/CLP operational activities based on the period 2010 to the present. When applied to the estimates of expenditure under the future scenarios, this provides estimates of staff costs.

In turn, building costs are likely to be somewhat linked to staff and, as such, these have been linked to calculated staff costs in the same way.

4.4 ECHA's projected expenditure and revenue under the scenarios

4.4.1 Overview

This section provides an overview of the total expenditure and revenue for ECHA under the scenarios described above, namely:

- Baseline scenario
- Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years
- Evaluation expanded to all >1000t substances using current screening strategy applied only to lead and individual registration dossiers over 10 years
- Evaluation expanded to all >1000 using higher levels of scrutiny applied to all dossiers (lead, member and individual) over 20 years
- Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years

The brief discussion is divided into consideration and comparison of estimated total expenditure and then revenue from REACH/CLP fees and charges and, finally, the EU balancing budget, which makes up the shortfall between expenditure and revenue from fees and charges.

A detailed breakdown of each of the estimates has been provided as Appendix A which, for each of the five scenarios (including the baseline) provides the underlying estimates of:

- REACH/CLP operational expenditure – broken down by task
- Total expenditure on REACH/CLP activities – broken down by staff costs and total operational costs
- Revenue from REACH/CLP fees and charges – broken down by source
- Total revenue by source – revenue from fees and charges plus the magnitude of the balancing budget required to offset expenditure

4.4.2 ECHA's expenditure under the baseline and scenarios

Figure 5 provides ECHA's estimated total expenditure under the baseline and each of the scenarios. The total expenditure is comprised of operational expenditure on REACH/CLP and costs of staff, buildings and equipment. The former is comprised of activities in relation to:

- Registration, datasharing and dissemination;
- Evaluation;
- Risk Management;
- Classification and labelling;
- Advice and assistance through guidance and helpdesk;
- Scientific IT tools;
- Scientific and technical advice to EU institutions and bodies; and
- Other operational activities cross cutting, international, horizontal and multi-annual reporting activities.

As can be seen from the underlying breakdowns of costs in Appendix A, staff costs make up around 60% of the total expenditure under all scenarios and time periods. This is because, even though the cost model is only varying engagement in the above activities (and in particular, evaluation), increased (or decreased) engagement in these activities acts to vary staff (and building/equipment) costs.

From Figure 5, under the baseline scenario costs fall from around €90m per year in the present/short term to around €77m per year in the longer term, where this is largely associated with the end of registration and the tailing off of late registrations for phase-in substances and associated work, a reduction in the effort needed in the medium and long term in relation to advice and assistance through the helpdesk and a reduction in work on risk management (restrictions and authorisations) in the longer term (with a slight reduction in the medium term relative to the present). Work on substance and dossier evaluation also reduces slowly over time as the 5% over 5 years target is met for 2018 substances in the short term and the intensive efforts to undertake completeness checks becomes reduced over the medium and long-term.

In contrast to some of these changing work and expenditure requirements over the short, medium and long-term, under some of the operational cost elements are likely to remain largely the same as at present. For example, expenditure on scientific IT tools is likely to remain fairly constant at the present level of circa. €10m per year because continuing update and maintenance of REACH IT and other tools is likely to be necessary into the future to preserve functionality and maintain the security of the data. Work on other activities such as cross cutting, international, horizontal and multi-annual reporting activities is also likely to remain unchanged and around the current level of €7.5m per year.

With the exception of costs for evaluation and registration and datasharing, the operational costs under all four alternative scenarios are identical to those under the baseline.

As such, any variation in the total expenditure between the baseline and each of the scenarios is associated only with:

- The increased efforts required for evaluation to be expanded to all >1000t substances (where this varies from one scenario to another);
- The increased work that this expanded evaluation activity generates in relation to registration work. Here, the evaluations are likely to identify failings in dossiers that need to be corrected via dossier updates. This work comes under the title of registration, datasharing and dissemination and, so, there is an increase in workload under this title; and
- Changes in staff and building costs consistent with increased efforts above.

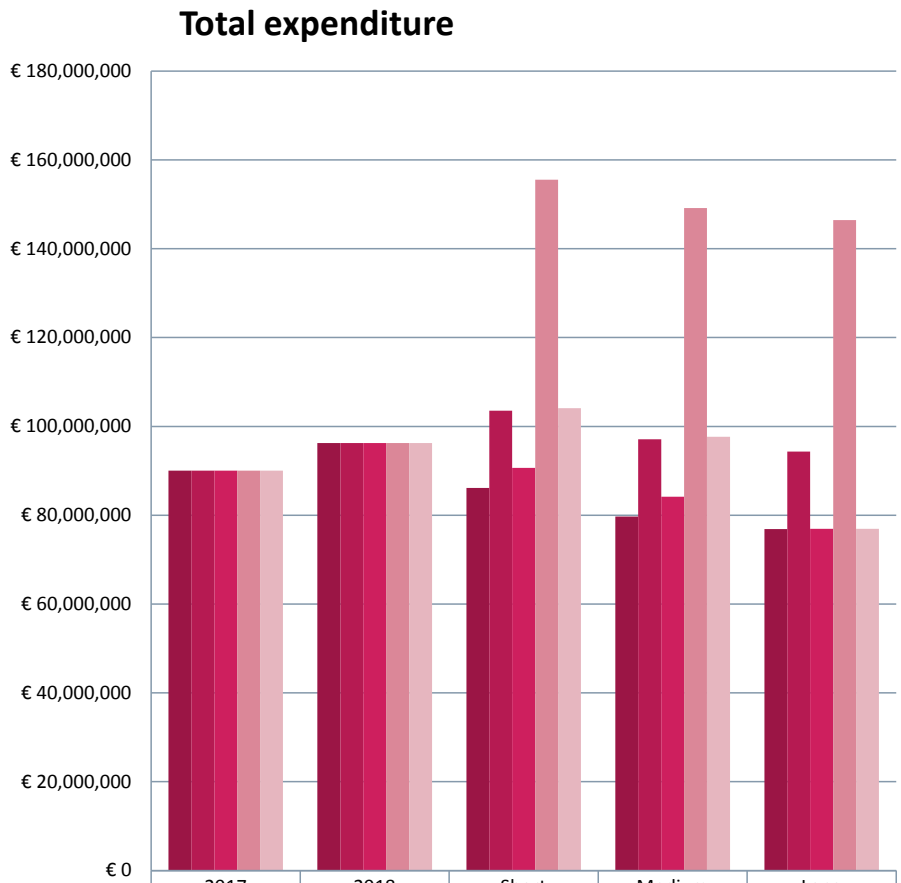
The variation between the different scenarios for >1000t substances relates only to the intensity of the scrutiny (current screening strategy versus higher level of scrutiny at higher cost), the number of dossiers scrutinised (all dossiers versus lead and individual only) per year and the length of time it would take to complete evaluation of all of the dossiers. These factors, in turn, act to increase costs to various degrees.

As can be seen from the figure, the 10 year expanded evaluation scenario using the current screening strategy applied to only lead and individual dossiers presents only a moderate increase in costs relative to the baseline of around €5m per year in the short and medium term. In the longer term, costs are comparable with those under the baseline (because the evaluation is completed by that time).

Moving up a scenario by applying this same searching strategy but increasing the level of scrutiny applied to the evaluations increases costs relative to the baseline by around €8-9m per year over the short to medium-term but, as above, in the longer term, costs are comparable with those under the baseline (because the evaluation is completed by that time).

For the two scenarios based on evaluations of all dossiers for >1000t substances costs estimated by the model are significantly higher than the baseline (and the other expanded evaluation scenario) and higher for a longer period. The evaluations are spread over a longer 20 year period because of the large number of dossiers to consider. The model suggests additional costs (relative to the baseline) of some €18m per year over the short, medium and long term for the evaluation using the current screening approach and some €70 for the approach using greater scrutiny. That said, these numbers need to be viewed with some caution. Owing to restricted study time and budget the model is relatively simplistic, applying simple statistically derived costs to each evaluation and treating all evaluations as equal. In practice they are unlikely to be. For example, when comparing scenarios for all dossiers versus those for lead and individual only there is a significant difference in costs. This is associated only with the need to assess dossiers of the members of a consortium as well as those for the lead. In this simple model, the cost of evaluating a lead dossier and a member dossier are the same. In practice, lead and member dossiers will have identical/very similar entries for the physicochemical, toxicological and ecotoxicological information required REACH Annexes VII to X and may only differ in terms of administrative information and CSA/CSR. As such, once the lead dossier has been evaluated, the evaluation of the member dossiers should require much less effort and, in a more complex model, the costs would reflect this reduced effort. Therefore one can conclude that expenditure on these options may not be as high as indicated in this simple model (but still higher than the scenario where lead and individual dossiers only are evaluated).

Figure J: Estimated total ECHA expenditure under the scenarios



	2017	2018	Short	Medium	Long
Baseline	€ 90,023,201	€ 96,231,551	€ 86,147,000	€ 79,678,000	€ 76,908,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - all dossiers over 20 years	€ 90,023,201	€ 96,231,551	€ 103,504,000	€ 97,087,000	€ 94,347,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - lead and individual dossiers over 10 years	€ 90,023,201	€ 96,231,551	€ 90,646,000	€ 84,188,000	€ 76,935,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - all dossiers over 20 years	€ 90,023,201	€ 96,231,551	€ 155,532,000	€ 149,138,000	€ 146,415,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - lead and individual dossiers over 10 years	€ 90,023,201	€ 96,231,551	€ 104,121,000	€ 97,677,000	€ 76,951,000

Source: For 2017-2018, ECHA budget reports. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

4.4.3 ECHA's revenue from REACH/CLP fees and charges

Figure 6 provides matching data on expected revenue generated under the baseline and scenarios that have been described above. In all periods and under all scenarios, fees under the heading of registration and updates make up the vast majority (90% and more) of fee income. The decline in income from the present to the longer-term is almost entirely due to the completion of registration of phase-in substances in 2018. The bulk of continuing income under all scenarios (again around 90%) is owing to a low level of new substance registration (which is the same across all scenarios) and fees for updates. The latter (updates) varies from one scenario to another and this is responsible for the vast majority of the variation between scenarios because of the link between evaluation and updates.

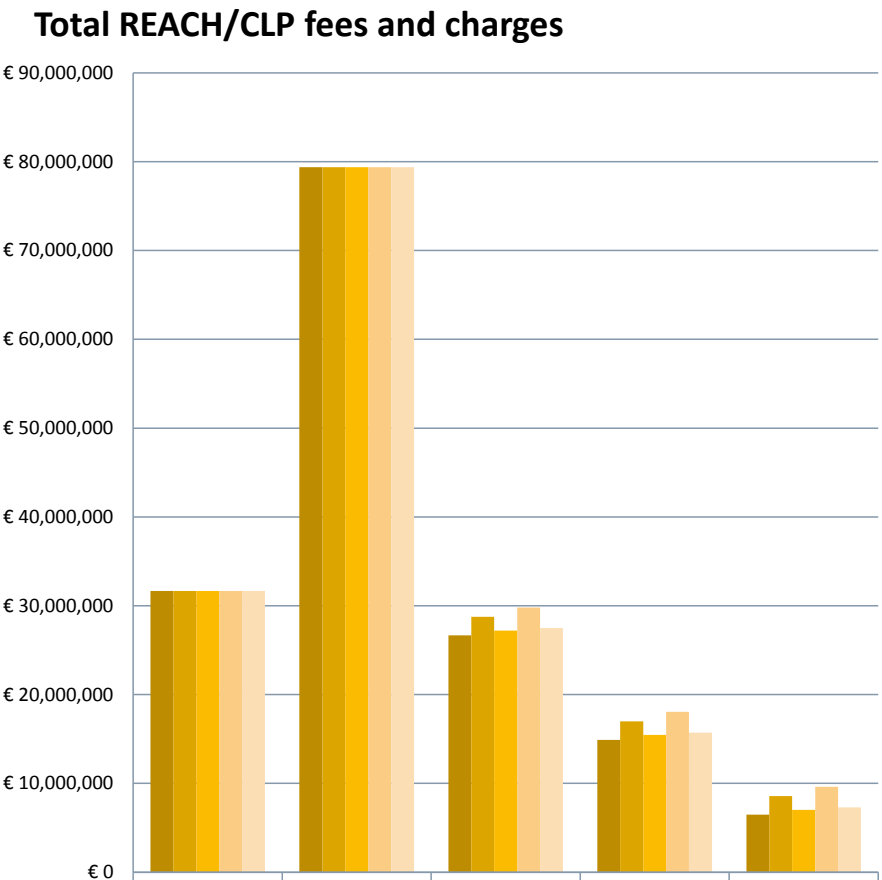
Here, increased and expanded evaluation of >1000t substances, while requiring additional expenditure (as described in the previous section), also generates more updates to correct errors and gaps which, in turn, generates more fees. These same evaluation decisions generate more appeals for which fees are also charged.

As with the modelling of expenditure, owing to the constraints of time and budget, the estimates of revenue from fees/charges are based on a simple model. The actual fees for updates vary significantly depending on the type of update (such as whether it is an update of administrative information or more significant update of, say, a data endpoint). In the simple model a single cost of update has been applied for each size of company/type of dossier (joint/individual) where this has been statistically derived from what little data is available on existing reasons for updating. In practice, between scenarios, the type of update will vary just as the number varies. So, for example, the updates required in response to evaluation of >1000t substances by ECHA may be more comprehensive and incur larger fees than has been assumed in the simple model. Thus, the returns in fee income from an increase in evaluation may be underestimated in the analysis.

In addition, as with the modelling of expenditure, the link between lead and member dossiers is not fully explored in detail in the model. In the case of fees and charges, for scenarios where there is evaluation of only member and individual dossiers for >1000t substances, no account has been taken of the need for member dossiers to also submit updates where the lead dossier has been found lacking by ECHA. As such, under these (10 year) scenarios the fee income may actually be closer to that of scenarios where all dossiers are evaluated (because member registrants may also have to submit updates and incur a fee).

In spite of these limitations of the model, however, the variation between baseline and scenarios (and between scenarios) is relatively small. This would be greater if more consideration could be given to the type (and fee cost) of update but, when compared with the levels of expenditure required (of the order of €100m plus per year), the impact on the balance between expenditure and revenue is likely to be relatively small.

Figure K: Estimated total ECHA revenue from REACH/CLP fees and charges under the scenarios



	2017	2018	Short	Medium	Long
Baseline	€ 31,664,289	€ 79,383,077	€ 26,667,000	€ 14,909,000	€ 6,488,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - all dossiers over 20 years	€ 31,664,289	€ 79,383,077	€ 28,758,000	€ 16,996,000	€ 8,576,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - lead and individual dossiers over 10 years	€ 31,664,289	€ 79,383,077	€ 27,210,000	€ 15,450,000	€ 7,030,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - all dossiers over 20 years	€ 31,664,289	€ 79,383,077	€ 29,809,000	€ 18,045,000	€ 9,626,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - lead and individual dossiers over 10 years	€ 31,664,289	€ 79,383,077	€ 27,485,000	€ 15,725,000	€ 7,305,000

Source: For 2017-2018, ECHA budget reports. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

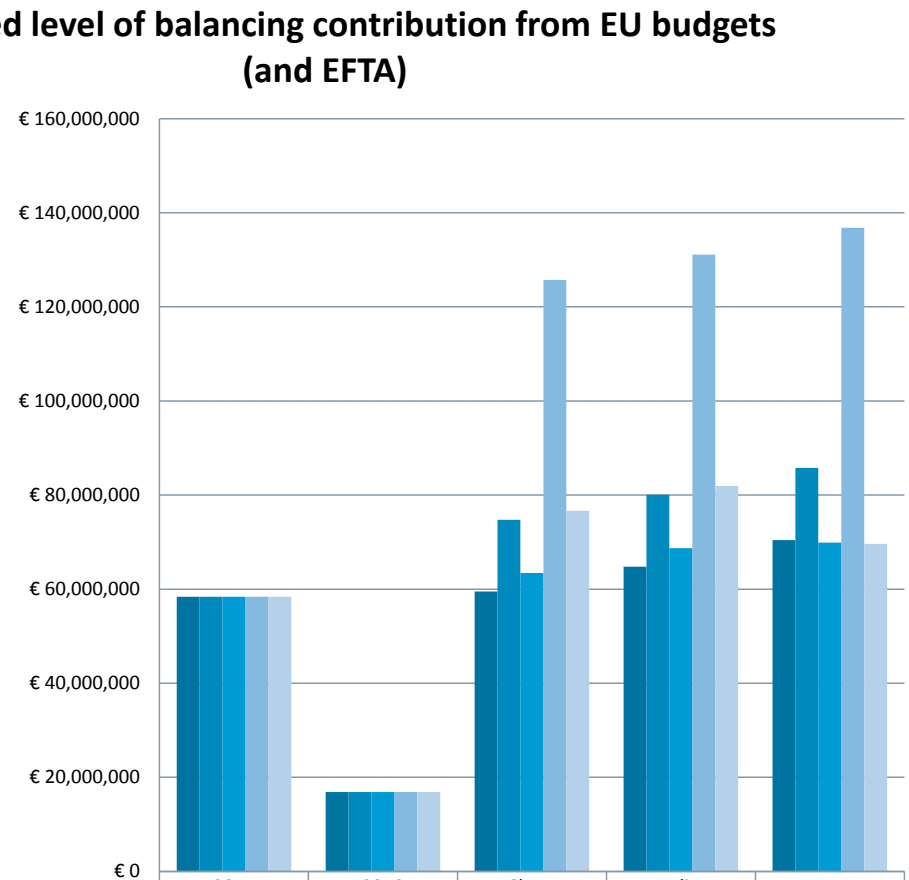
4.4.4 Balancing the budget

From the discussion above on ECHA expenditure under the baseline and scenarios and the revenue from fees and charges it is clear that there is a large gap between the two. Under the current arrangements this gap is filled by the commitment to fund the deficit from a contribution from the EU budget. The magnitude of the EU budget contributions required to fill the deficits under the baseline and scenarios is provided as Figure 7.

As can be seen from these data, under the baseline and all scenarios and increase or a substantial increase in EU budget contributions is required to ensure continued support of

ECHA to achieve the political objectives of REACH. The next section considers some options for future finance options for ECHA that would seek to reduce/eliminate the deficit by self-financing and, in the process reduce EU budget contributions.

Figure L: EU Balancing Budget contributions under the scenarios



	2017	2018	Short	Medium	Long
Baseline	€ 58,358,912	€ 16,848,474	€ 59,480,000	€ 64,769,000	€ 70,420,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - all dossiers over 20 years	€ 58,358,912	€ 16,848,474	€ 74,746,000	€ 80,091,000	€ 85,771,000
Dossier evaluation expanded to all >1000t substances using current screening strategy - lead and individual dossiers over 10 years	€ 58,358,912	€ 16,848,474	€ 63,436,000	€ 68,738,000	€ 69,905,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - all dossiers over 20 years	€ 58,358,912	€ 16,848,474	€ 125,723,000	€ 131,093,000	€ 136,789,000
Dossier evaluation expanded to all >1000t substances using higher scrutiny - lead and individual dossiers over 10 years	€ 58,358,912	€ 16,848,474	€ 76,636,000	€ 81,952,000	€ 69,646,000

Source: For 2017-2018, ECHA budget reports. See https://echa.europa.eu/about-us/the-way-we-work/financial-management-and-budgetary-reporting/2018

5 Future Finance options

5.1 Overview

It is clear from the data in Figure 7 and the discussion in Section 4.4 that, under all scenarios as well as the baseline, there is a significant gap between the revenue from fees and charges for REACH/CLP and expenditure on REACH/CLP activities, staff and buildings. Under all scenarios this gap becomes larger over time with the result that, without intervention to change the existing mechanisms for REACH fees and charges, the EU balancing budget contribution will need to increase over time to fund ECHA's efforts to deliver REACH political objectives. In the light of possible additional responsibilities (such as the creation of a new database on SVHCs under the Waste Framework Directive and the creation of a searchable database for information on mixtures in case of emergency health response) further pressure may be placed on ECHA's resources, further increasing the need to secure supplementary sources of funding.

The study has considered several alternatives approaches and mechanisms that would increase revenue from ECHA activities and, in the process reduce/eliminate the gap (and therein the EU budget contribution), and correct the obvious imbalance between the cost of ensuring compliance with REACH (and the objectives of REACH) and the revenue from the fee mechanisms that were originally envisaged.

When considering how this might be achieved the study has sought to draw on (and ensure that options are consistent with) funding models of other EU agencies. As part of the study, a review of funding methods applied in other EU has been undertaken. This review is provided as Appendix B to this report and the key conclusions of the review are that:

- while the majority of EU agencies are fully funded from the EU budget, some depend (to varying degrees) on other sources of funding, including industry fees/charges or contributions from national authorities;
- the analysis indicates that the European Aviation Safety Agency (EASA) and the European Medicines Agency (EMA) are the two agencies that are most similar to ECHA in terms of their sources of funds. EASA, EMA and ECHA all combine income from fees with contributions from the EU budget;
- the charging of fees has a number of advantages, including[21] ensuring that there is demand for the service provided and high quality of service delivery, a direct link between service use and funding, and a reduced pressure on the EU budget;
- a prerequisite for charging fees to industry is the provision of services to industry;
- the degree of transparency provided to industry stakeholders varies widely (EASA vs EMA); and
- different agencies rely on different fee models (e.g. flat fees, variable fees, annual fees, etc.), each of which has distinct advantages and disadvantages.

[21] European Parliament (2018): Specifications for an analytical study for the Committee on Budgets, "Potential revenue from the extension of charging fees by EU Agencies", available at: https://www.politico.eu/wp-content/uploads/2017/11/SPOLITICO-17111611370.pdf

On the basis of these findings and consideration of the mechanisms and objectives of REACH/CLP the following alternatives have been considered:

- **A new annual charge/fee requirement:** where existing fee mechanisms were intended to cover the costs of completeness checking, evaluation, etc. the evidence presented in the sections above suggests that they do/have not. This measure builds on the original 'one off' registration fee and converts it into fee charged on an annual basis that covers the ongoing costs of the regulator (ECHA), to undertake its activities under REACH/CLP. This could replace existing fees for updates (and so no update fees would apply) where this would be consistent with encouraging (or rather not discouraging) submission of updates to dossiers. Alternatively, existing fees for updates could remain in place. The option is explored in more detail later in this section;
- **A new update requirement:** A new requirement could be introduced that would require periodic updates to be made to registration dossiers. The aim of this would be to increase the quality of dossiers while increasing revenue to ECHA from update fees. The option is explored in more detail later in this section;
- **Implement charges for updates triggered by ECHA evaluation:** Connected with the scenarios for extending evaluation to all >1000t substances (as opposed to the target of 5% of dossiers), this option would seek to pass on the costs of the evaluation to registrants found to be non-compliant by raising charges connected with non-compliant endpoints. The option is explored in more detail later in this section; and
- **Introduce charging for access to 'enhanced' data services:** ECHA are in possession of a large amount of data and provide access to a number of online databases. As part of the study we have given some consideration to how and what ECHA could charge for access to however this option was found to be problematic. Articles 118 and Article 119 of REACH are clearly set out that all available information should be made freely available online. In addition, the availability of (free) information is important to delivering the political objectives of REACH. As such, charging for any data that is useful to that end is not consistent with the objectives of REACH and ECHA's duties. As such, the option was eliminated and not considered in detail.

5.2 A new regular annual charge/fee requirement

In terms of the first of these, as noted above, this measure builds on the original 'one off' registration fee and converts it into fee charged on an annual basis that covers the ongoing costs of the regulator (ECHA), to undertake its activities under REACH/CLP. As such, under the measure, a company would pay an annual registration renewal fee for each new and phase-in substance that it has registered.

Using data on numbers of REACH registrations by tonnage and company sizes we have calculated the level of fee applied to registrations that would be required to generate €100m of revenue per year. The calculated fee rates are provided in Table 3.

As can be seen from the table, fees vary by company size, tonnage band and type of registration. The distribution of fees by these criteria is in the same proportion to that of the existing registration fees.

Table 3: Annual fee per dossier to deliver €100million per year

	Large	Medium	Small	Micro
1-10t	€ 199	€ 129	€ 70	€ 10
10-100t	€ 535	€ 348	€ 187	€ 27
100-1000t	€ 1,432	€ 931	€ 501	€ 72
>1000t	€ 3,860	€ 2,509	€ 1,351	€ 193
Intermediate	€ 174	€ 113	€ 61	€ 9

In spite of the fact that calculated fees appear small in scale (from tens of Euros per substance for micro companies and 1-10t substances to €3.8k thousand euros per substance for large enterprises and >1000t substances), once applied to the total numbers of registrations they have the potential to generate very significant revenue. It should be noted here that €100m was used as the target figure only for the purposes of calculation and the study is not proposing that this is the level at which it should be set, particularly as it is greater than calculated expenditure under most of the scenarios. The value was selected both because it represents a large sum of the right order of magnitude and because it is easy to extrapolate to different fee rates required to generate a different value. Thus, 80% of each of the fee rates would generate around €80m of revenue, as shown in Table 4.

Table 4: Annual fee per dossier to deliver €80million per year

	Large	Medium	Small	Micro
1-10t	€ 159	€ 103	€ 56	€ 8
10-100t	€ 428	€ 278	€ 150	€ 22
100-1000t	€ 1,146	€ 745	€ 401	€ 58
>1000t	€ 3,088	€ 2,007	€ 1,081	€ 154
Intermediate	€ 139	€ 90	€ 49	€ 7

What the total annual cost of the new fee would be for different companies clearly depends on the number of substances registered by each company. Using average data on numbers registered by tonnage for companies of different sizes the statistical average company would pay annual fees at the levels in Table 5.

Table 5: Average annual fee per company (calculated using data on numbers of substances registered at different tonnages by company size provided to the study by ECHA)

	Large	Medium	Small	Micro
Average annual fee to deliver €100million per year	€ 10,572	€ 3,147	€ 1,102	€ 109
Average annual fee to deliver €80million per year	€ 8,458	€ 2,518	€ 882	€ 87

The study also considered the scope for using such a fee as an incentive to update dossiers. Here the Commission's recent REACH Review[22] identified that non-compliance of registration dossiers was one of (the four) issues requiring most urgent action and "*encourage updating of registration dossiers*" is Action 1 from the Review. Whilst it is known that COM/ECHA would like companies to update their registration dossiers regularly, fees for updating registration may act as a disincentive. As such, we considered:

- the possibility of eliminating fees for updates and substituting them with an annual registration renewal fee; and
- whether one could incentivise certain desirable types of dossier update (e.g. additional (eco)toxicological information) by waiving the annual renewal fee whenever an update is made or by introducing a concept of 'dossier certification' such that once dossiers have been checked and certified as complete and satisfactory by ECHA they would no longer incur an annual fee.

It was decided that the second of these was unrealistic and overly complex but we have estimated the impact of eliminating fees for updates and replacing them with the annual fee. Here we estimate that, from the above, introducing an annual fee at the rates described above would generate €100m of revenue. Eliminating fees for updates under the baseline would reduce total fee revenue by around €11m. Thus, total fee revenue for ECHA under this scenario would be of the order of €89m. The average net increase in fees for the statistical average company relative to the current situation is provided in Table 6.

Table 6: Net average annual fee per company with the elimination of update fees

	Large	Medium	Small	Micro
Average annual fee (based on numbers of substances registered at different tonnages)	€ 10,572	€ 3,147	€ 1,102	€ 109
Net increase in fees by waiving update fees	€ 8,221	€ 2,264	€ 771	€ 79

In terms of the practicalities of applying a new annual fee, a potential concern is that the administrative cost involved in raising thousands of small invoices annually might be as high as the value of the invoices themselves. However, as with registration fees, it seems possible that the fee could be invoiced automatically via REACH IT. If this were the case (or could be made to be the case), the aggregate administrative burden may not be high, especially if all substance renewals for a given company were invoiced together.

5.3 A new update requirement

In terms of options for a new requirement to update regularly, this would require that periodic updates are made to registration dossiers where, again, this is consistent with conclusions from the Commission's recent REACH Review which identified that non-compliance of registration dossiers was one of (the four) issues requiring most urgent action and "*encourage updating of registration dossiers*" is Action point 1. This new update requirement would have the aim of

[22] https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

increasing the quality of dossiers while at the same time increasing revenue to ECHA from update fees.

Three different scenarios for update frequency were considered. Here, revenue (and therefore costs to industry) of 3, 5 and 10 year periodic updates of all registration dossiers was estimated based on a constant flow of updates (as opposed to bulk submissions coinciding with the update frequency). The total revenue generated and the distribution of costs between companies of different sizes is provided in Table 7. As can be seen from the table, as update frequency is currently (estimated to be) around 10% per year under the baseline, this is equivalent to an update frequency of 10 years and so revenue, in the short term, is likely to be the same/similar. In the longer term under the baseline, however, if the frequency of annual updates to dropped below 10% under the baseline there would be a reduction in fee revenue from updates in the future. This would not occur with an obligatory 10 year update but, at the same time, the revenue generated is still unlikely to offset the total expenditure and the EU budget contributions. A three year update frequency would generate more revenue but even this is relatively modest compared with ECHA expenditure and the EU budget contributions.

Table 7: Revenue and industry costs from new requirements to periodically update dossiers

Update frequency (years)	Total fee revenue	Large enterprises	Medium enterprises	Small enterprises	Micro enterprise
Current	**€ 10,959,199**	€ 10,126,197	€ 660,287	€ 106,120	€ 66,595
3	**€ 36,530,664**	€ 33,753,991	€ 2,200,956	€ 353,732	€ 221,984
5	**€ 21,918,398**	€ 20,252,395	€ 1,320,574	€ 212,239	€ 133,190
10	**€ 10,959,199**	€ 10,126,197	€ 660,287	€ 106,120	€ 66,595

The annual cost of the periodic update options for average companies of different size has been estimated and is provided in Table 8. This provides only the cost of paying fees and not the costs of updating dossiers themselves. The study timescale and budget has not allowed this to be modelled in detail.

Table 8: Average annual cost of fees per company of different size - Fees only

Update frequency (years)	Large enterprise	Medium enterprise	Small enterprise	Micro enterprise
Current	€ 2,351	€ 883	€ 331	€ 31
3	€ 7,837	€ 2,942	€ 1,104	€ 103
5	€ 4,702	€ 1,765	€ 663	€ 62
10	€ 2,351	€ 883	€ 331	€ 31

5.4 Implement charges for updates triggered by ECHA evaluation

The final option considered is connected with the scenarios for extending evaluation to all >1000t substances. It seeks to address the issue that the work required by ECHA to identify non-compliance with dossiers through evaluation is intensive and time consuming and that the cost of these undertaken are not recouped by the initial registration fees or fees charged for updates at present. This option would seek to pass on the costs of the evaluation to registrants found to be non-compliant by raising charges connected with non-compliant endpoints.

The option has not been costed owing to time and budget constraints. However, some consideration has been given to how such charges could be implemented and their level set. Here, on the surface, it would seem relatively complicated to introduce a charging system that is sensitive to the type of non-compliance and update that is required. However, rather than introduce a totally new system of fees it seems sensible to suggest that an update fee multiplier could be introduced.

Here, update fees are already highly differentiated by type of update - with the end fee paid depending on the changes made to the dossier. The simplest way of recouping the costs of evaluation on non-compliant dossiers would seem to be to apply a multiplier to these fees for situations where the non-compliance has been identified by ECHA as opposed to being corrected by an update submitted by a registrant on their own initiative. Thus, at present if a large enterprise were to update information in the SDS for a substance for which it is the only registrant (individual registrant) it would incur a fee of €3,261 whether this was voluntary or whether the need for this had been identified by ECHA. Under a new charging system a multiplier would be applied to the update fee to reflect the costs of ECHA's evaluation work. If this multiplier were, for example, 5, then the fee due would be €16,305 rather than €3,261. Such an 'evaluation update charge multiplier' would encourage registrants to ensure that their dossiers are suitably complete, up to date and conform to the requirements and would appropriately penalise those that do not. In addition, by altering the balance between the effort required by ECHA to identify non-compliant dossiers and the revenue generated when one is identified, in purely financial/business terms, the effort is rewarded and costs of evaluation offset.

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A Breakdown of ECHA's estimated expenditure and revenue under the scenarios

A.1 Overview

The overall estimated expenditure and revenue for ECHA's activities under each of the scenarios has been provided and discussed in Section 4.4. This appendix provides a detailed breakdown of each of the estimates, providing the underlying estimates of:

- REACH/CLP operational expenditure – broken down by task
- Total expenditure on REACH/CLP activities – broken down by staff costs and total operational costs
- Revenue from REACH/CLP fees and charges – broken down by source
- Total revenue by source – revenue from fees and charges plus the magnitude of the balancing budget required to offset expenditure

The sub-sections below provide these data on each of the scenarios, namely:

- Baseline scenario
- Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years
- Evaluation expanded to all >1000t substances using current screening strategy applied only to lead and individual registration dossiers over 10 years
- Evaluation expanded to all >1000 using higher levels of scrutiny applied to all dossiers (lead, member and individual) over 20 years
- Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years

A.2 Breakdown of expenditure and revenue - Baseline scenario

The following figures provide the estimates and breakdowns of expenditure and fees under this scenario:

- Figure M: REACH/CLP operational expenditure - Baseline
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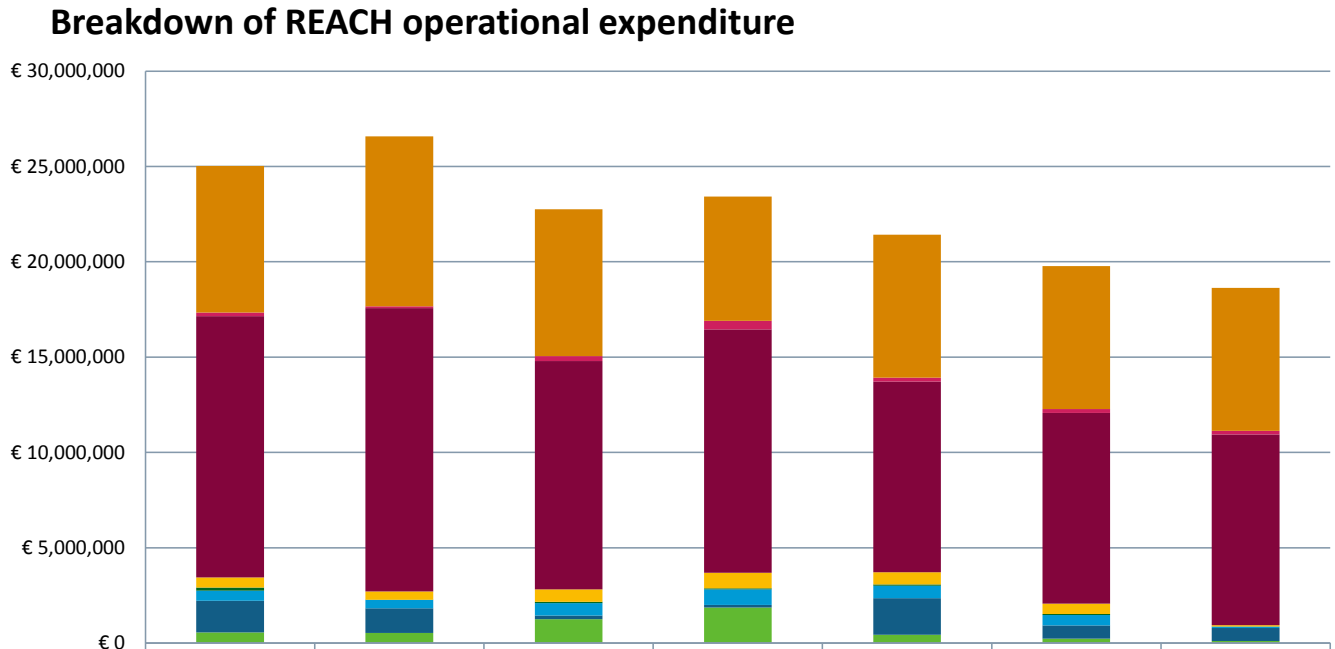
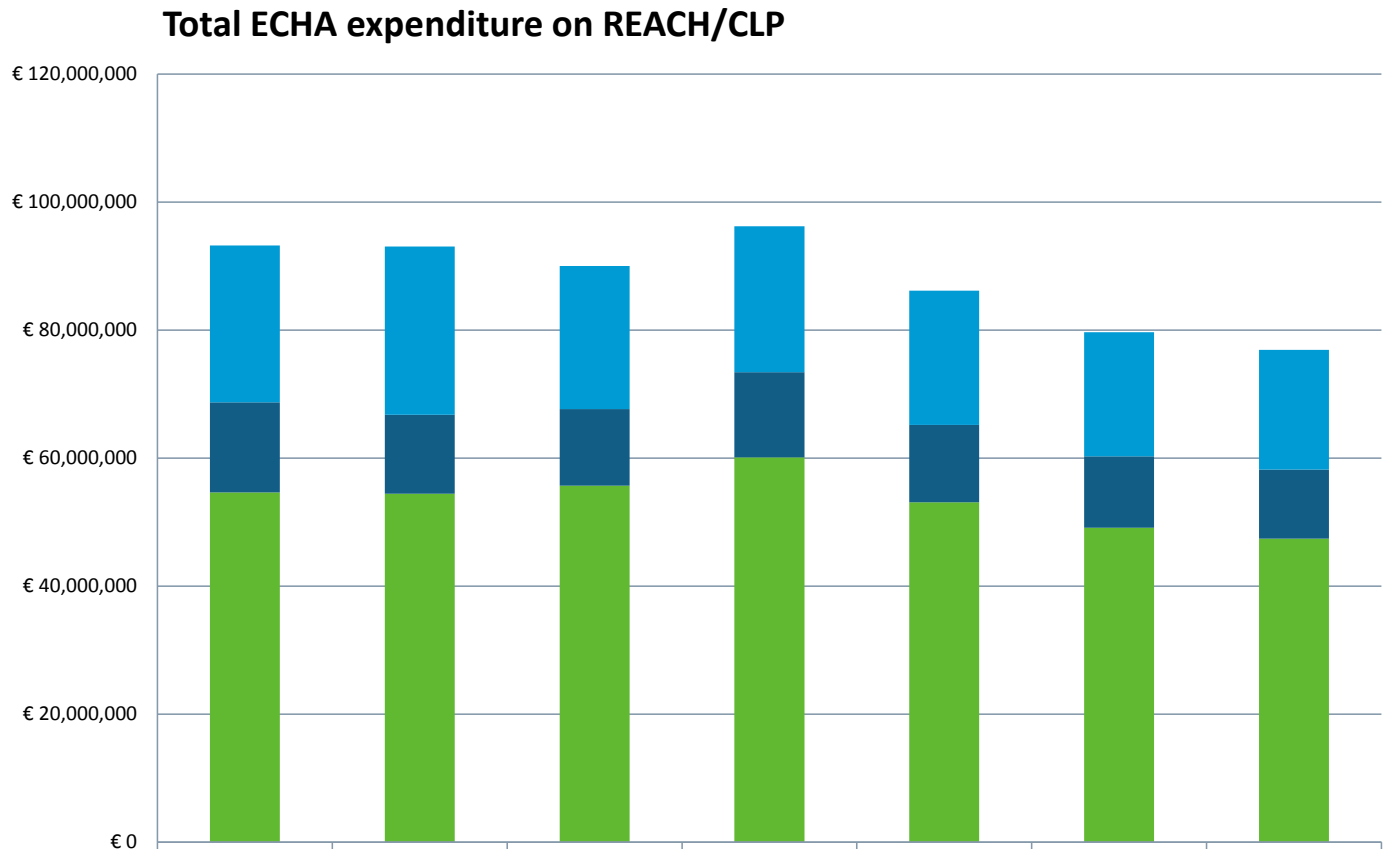
Figure M: REACH/CLP operational expenditure - Baseline



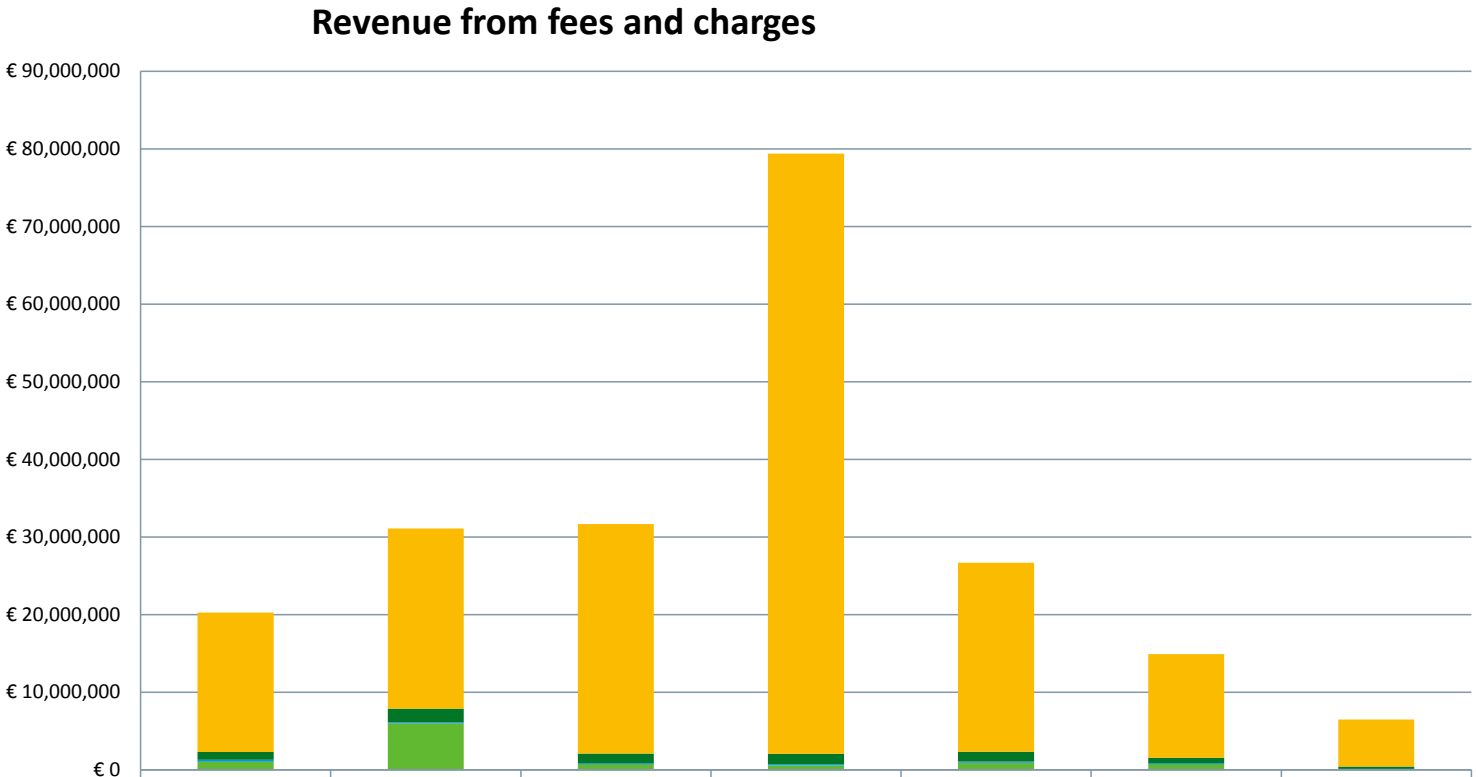
	2015	2016	2017	2018	Short	Medium	Long
Other operational activities cross cutting, international, horizontal and multi-annual reporting activities	€ 7,693,663	€ 8,912,339	€ 7,703,336	€ 6,518,624	€ 7,500,000	€ 7,500,000	€ 7,500,000
Scientific and technical advice to EU institutions and bodies	€ 188,689	€ 103,371	€ 259,000	€ 446,206	€ 200,000	€ 200,000	€ 200,000
Scientific IT tools	€ 13,704,528	€ 14,854,250	€ 11,978,562	€ 12,763,786	€ 10,000,000	€ 10,000,000	€ 10,000,000
Advice and assistance through guidance and helpdesk	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Classification and labelling	€ 154,965	€ 13,194	€ 64,218	€ 48,285	€ 67,000	€ 57,000	€ 15,000
Risk Management	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Evaluation	€ 1,654,669	€ 1,295,374	€ 195,273	€ 136,000	€ 1,922,000	€ 689,000	€ 689,000
Registration, datasharing and dissemination	€ 562,988	€ 533,989	€ 1,254,168	€ 1,865,491	€ 431,000	€ 236,000	€ 108,000

Figure N: Total expenditure on REACH/CLP activities - Baseline



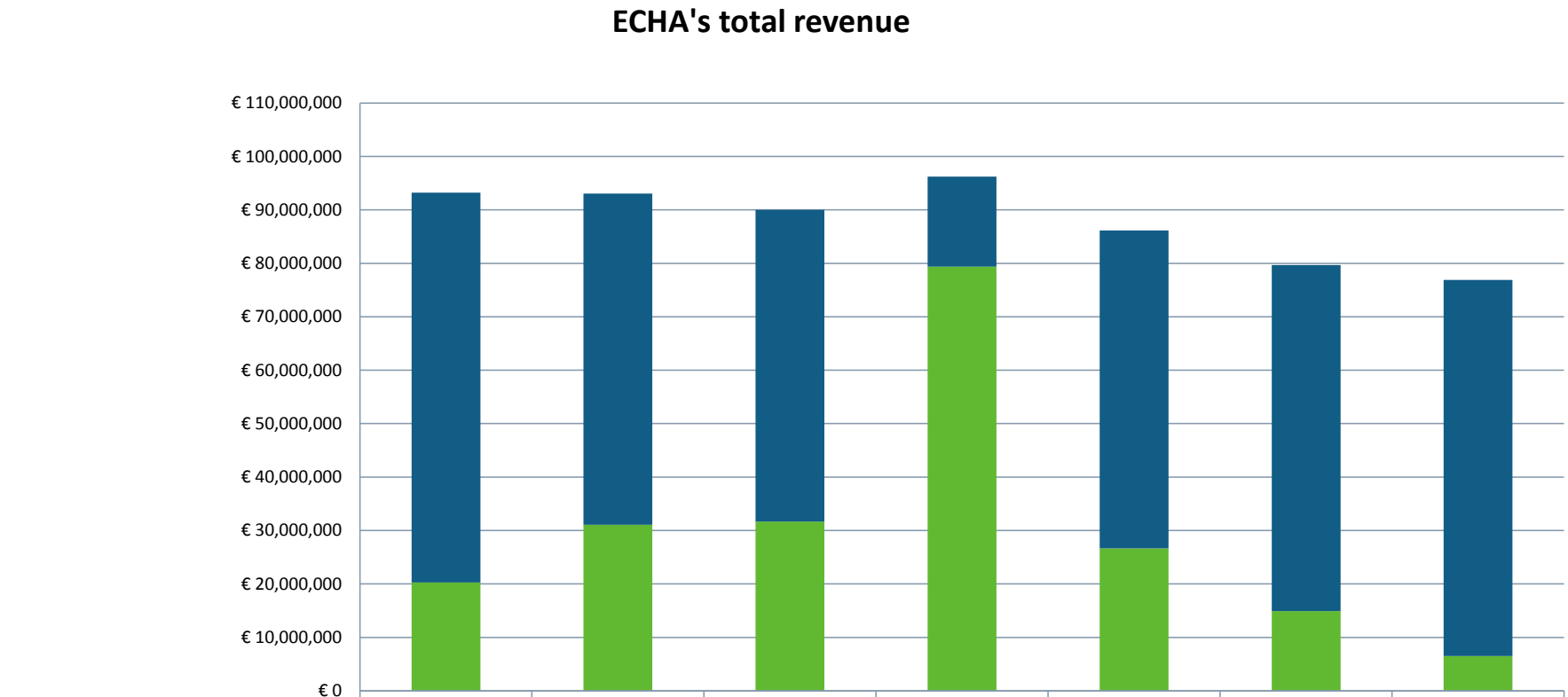
	2015	2016	2017	2018	Short	Medium	Long
REACH operating expenditure	€ 24,495,700	€ 26,309,440	€ 22,356,362	€ 22,825,148	€ 20,971,000	€ 19,396,000	€ 18,722,000
Building, equipment and miscellaneous operating expenditure	€ 14,101,605	€ 12,347,132	€ 11,983,639	€ 13,285,047	€ 12,082,000	€ 11,175,000	€ 10,786,000
Staff	€ 54,618,876	€ 54,412,542	€ 55,683,201	€ 60,121,356	€ 53,094,000	€ 49,107,000	€ 47,400,000

Figure O: Revenue from REACH/CLP fees and charges - Baseline



	2015	2016	2017	2018	Short	Medium	Long
New sub Registration + updates + late registration	€ 17,955,000	€ 23,210,566	€ 29,553,000	€ 77,308,000	€ 24,329,000	€ 13,354,000	€ 6,052,000
Other fees and charges	€ 1,000,000	€ 1,750,000	€ 1,233,700	€ 1,357,000	€ 1,267,000	€ 696,000	€ 315,000
CLP	€ 229,000	€ 144,000	€ 148,613	€ 148,000	€ 147,000	€ 124,000	€ 34,000
Appeals	€ 7,069	€ 14,244	€ 14,315	€ 0	€ 57,000	€ 7,000	€ 3,000
Authorisation	€ 1,066,000	€ 5,961,449	€ 714,661	€ 570,077	€ 867,000	€ 728,000	€ 84,000

Figure P: Total revenue - Baseline



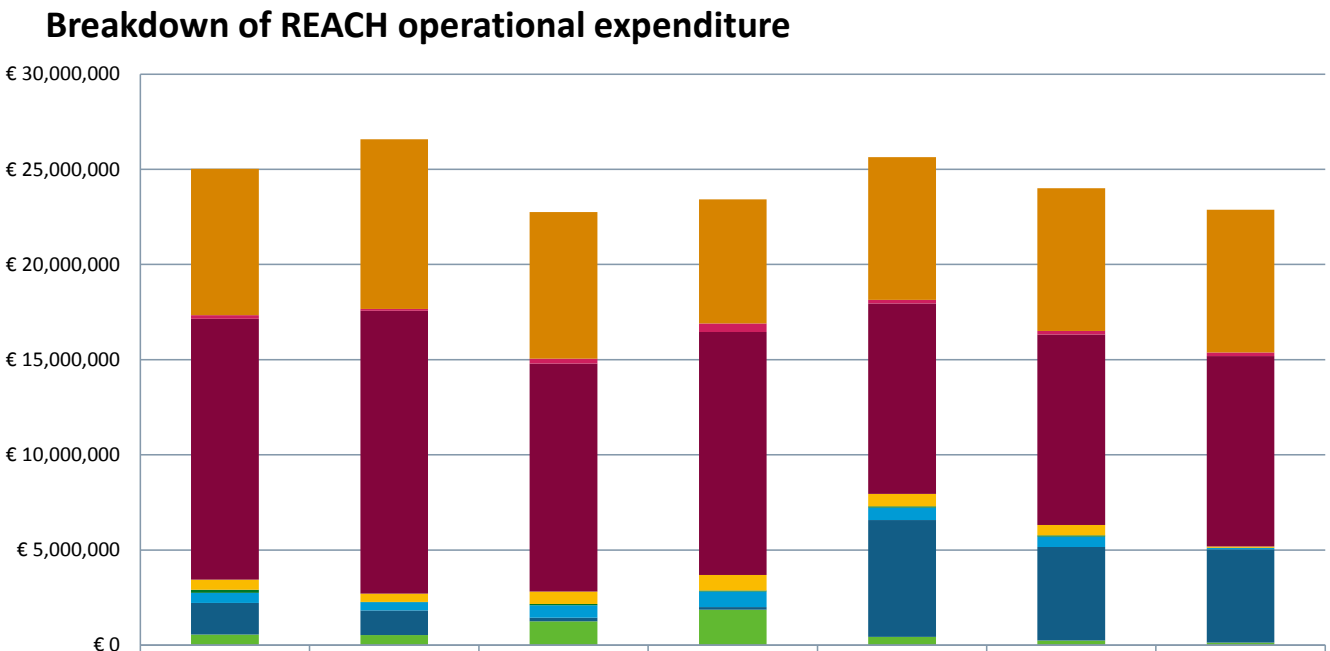
	2015	2016	2017	2018	Short	Medium	Long
Contributions from EU budgets (and EFTA)	€ 72,959,112	€ 61,988,855	€ 58,358,912	€ 16,848,474	€ 59,480,000	€ 64,769,000	€ 70,420,000
REACH/CLP fees and charges	€ 20,257,069	€ 31,080,259	€ 31,664,289	€ 79,383,077	€ 26,667,000	€ 14,909,000	€ 6,488,000

A.3 Expenditure and revenue - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years

The following figures provide the estimates and breakdowns of expenditure and fees under this scenario:

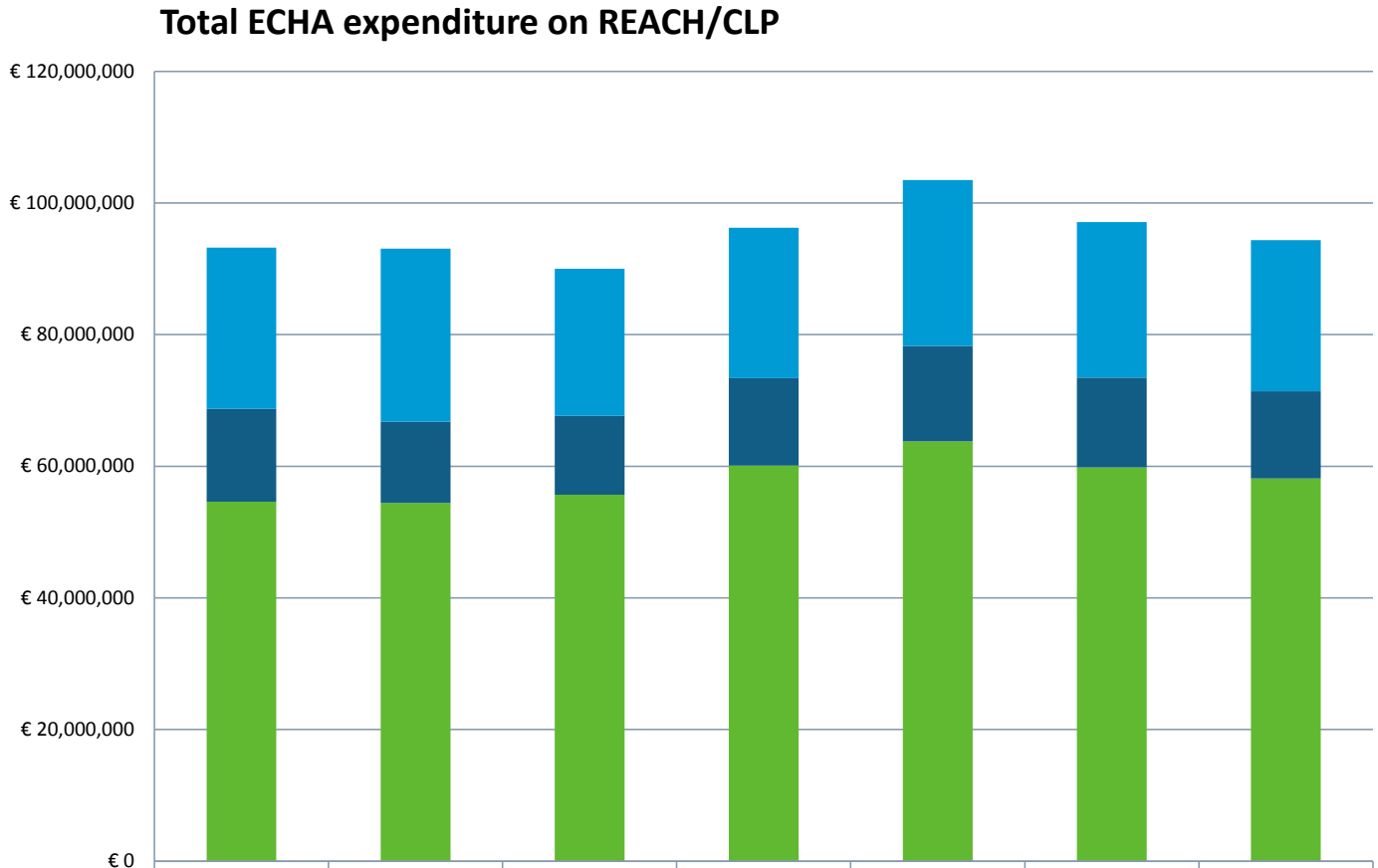
- Figure Q: REACH/CLP operational expenditure - Evaluation expanded to all >1000t substances using current screening strategy
- Figure R: Total expenditure on REACH/CLP activities - Evaluation expanded to all >1000t substances using current screening
- Figure S: Revenue from REACH/CLP fees and charges - Evaluation expanded to all >1000t substances using current screening
- Figure T: Total revenue - Evaluation expanded to all >1000t substances using current screening

Figure Q: REACH/CLP operational expenditure - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years



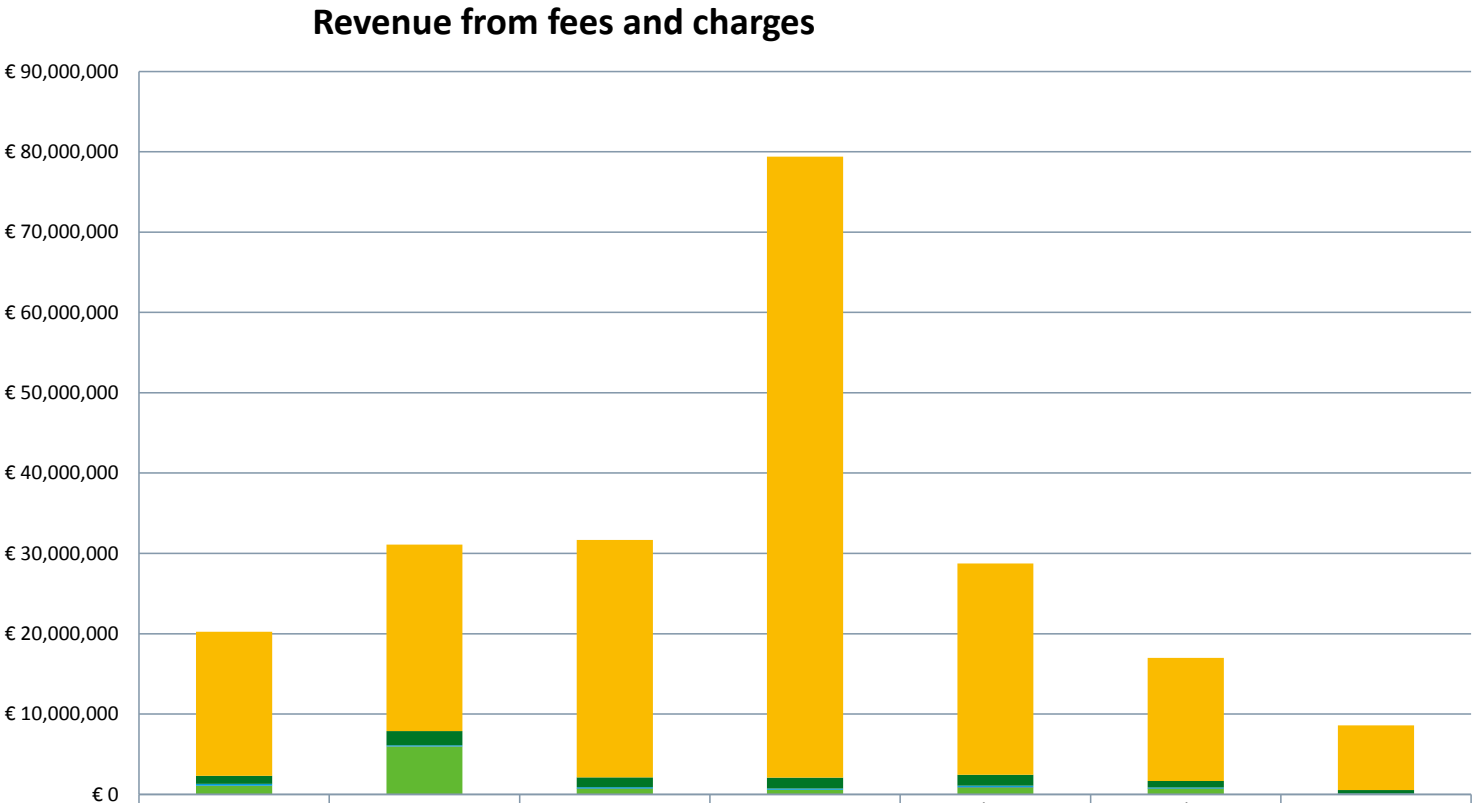
	2015	2016	2017	2018	Short	Medium	Long
Other operational activities cross cutting, international, horizontal and multi-annual reporting activities	€ 7,693,663	€ 8,912,339	€ 7,703,336	€ 6,518,624	€ 7,500,000	€ 7,500,000	€ 7,500,000
Scientific and technical advice to EU institutions and bodies	€ 188,689	€ 103,371	€ 259,000	€ 446,206	€ 200,000	€ 200,000	€ 200,000
Scientific IT tools	€ 13,704,528	€ 14,854,250	€ 11,978,562	€ 12,763,786	€ 10,000,000	€ 10,000,000	€ 10,000,000
Advice and assistance through guidance and helpdesk	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Classification and labelling	€ 154,965	€ 13,194	€ 64,218	€ 48,285	€ 67,000	€ 57,000	€ 15,000
Risk Management	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Evaluation	€ 1,654,669	€ 1,295,374	€ 195,273	€ 136,000	€ 6,143,000	€ 4,910,000	€ 4,910,000
Registration, datasharing and dissemination	€ 562,988	€ 533,989	€ 1,254,168	€ 1,865,491	€ 435,000	€ 253,000	€ 132,000

Figure R: Total expenditure on REACH/CLP activities - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years



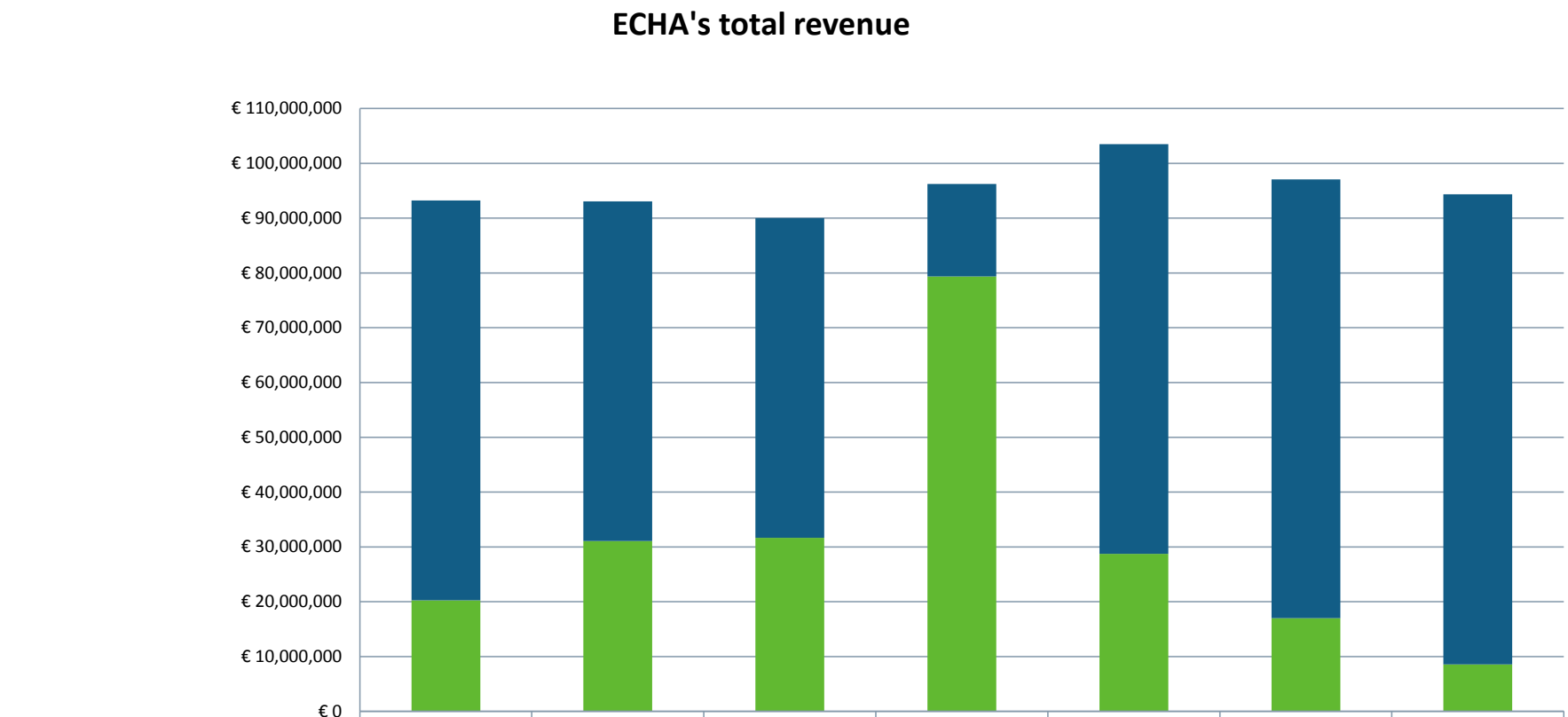
	2015	2016	2017	2018	Short	Medium	Long
REACH operating expenditure	€ 24,495,700	€ 26,309,440	€ 22,356,362	€ 22,825,148	€ 25,196,000	€ 23,634,000	€ 22,967,000
Building, equipment and miscellaneous operating expenditure	€ 14,101,605	€ 12,347,132	€ 11,983,639	€ 13,285,047	€ 14,516,000	€ 13,616,000	€ 13,232,000
Staff	€ 54,618,876	€ 54,412,542	€ 55,683,201	€ 60,121,356	€ 63,792,000	€ 59,837,000	€ 58,148,000

Figure S: Revenue from REACH/CLP fees and charges - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years



	2015	2016	2017	2018	Short	Medium	Long
New sub Registration + updates + late registration	€ 17,955,000	€ 23,210,566	€ 29,553,000	€ 77,308,000	€ 26,312,000	€ 15,337,000	€ 8,035,000
Other fees and charges	€ 1,000,000	€ 1,750,000	€ 1,233,700	€ 1,357,000	€ 1,371,000	€ 799,000	€ 419,000
CLP	€ 229,000	€ 144,000	€ 148,613	€ 148,000	€ 147,000	€ 124,000	€ 34,000
Appeals	€ 7,069	€ 14,244	€ 14,315	€ 0	€ 61,000	€ 8,000	€ 4,000
Authorisation	€ 1,066,000	€ 5,961,449	€ 714,661	€ 570,077	€ 867,000	€ 728,000	€ 84,000

Figure T: Total revenue - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years



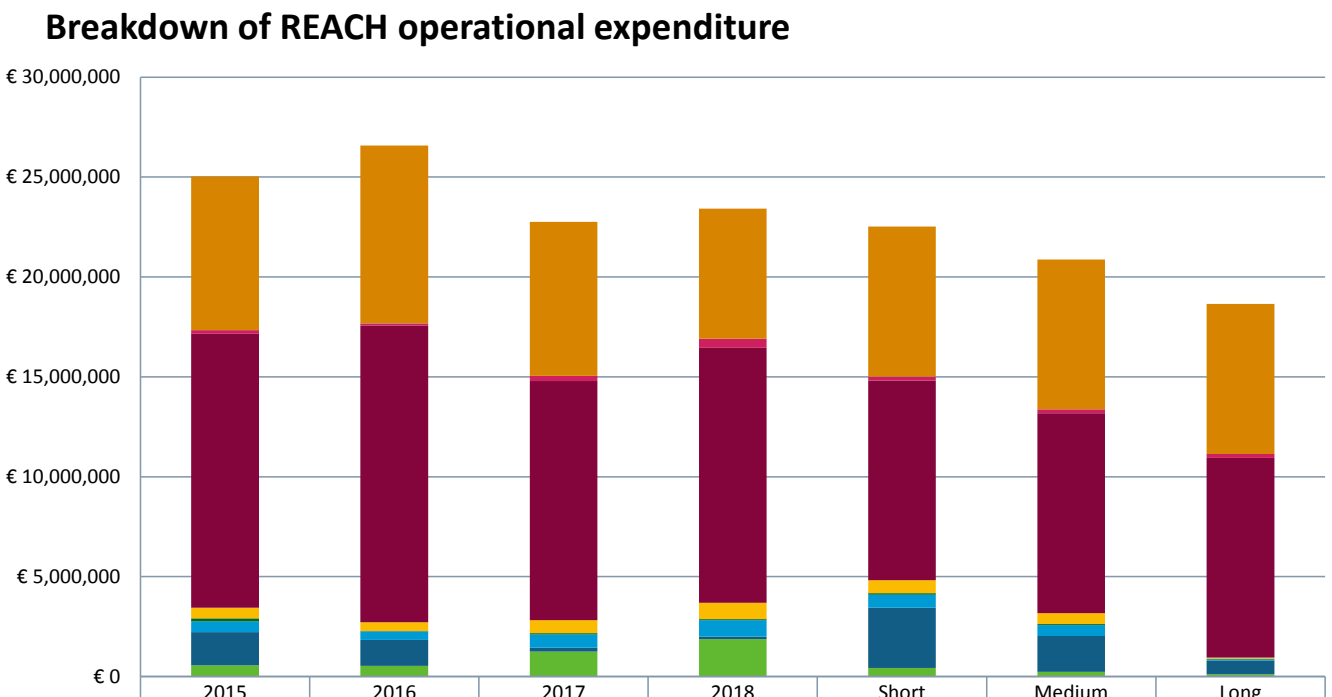
	2015	2016	2017	2018	Short	Medium	Long
Contributions from EU budgets (and EFTA)	€ 72,959,112	€ 61,988,855	€ 58,358,912	€ 16,848,474	€ 74,746,000	€ 80,091,000	€ 85,771,000
REACH/CLP fees and charges	€ 20,257,069	€ 31,080,259	€ 31,664,289	€ 79,383,077	€ 28,758,000	€ 16,996,000	€ 8,576,000

A.4 Expenditure and revenue - Evaluation expanded to all >1000t substances using current screening strategy applied only to lead and individual registration dossiers over 10 years

The following figures provide the estimates and breakdowns of expenditure and fees under this scenario:

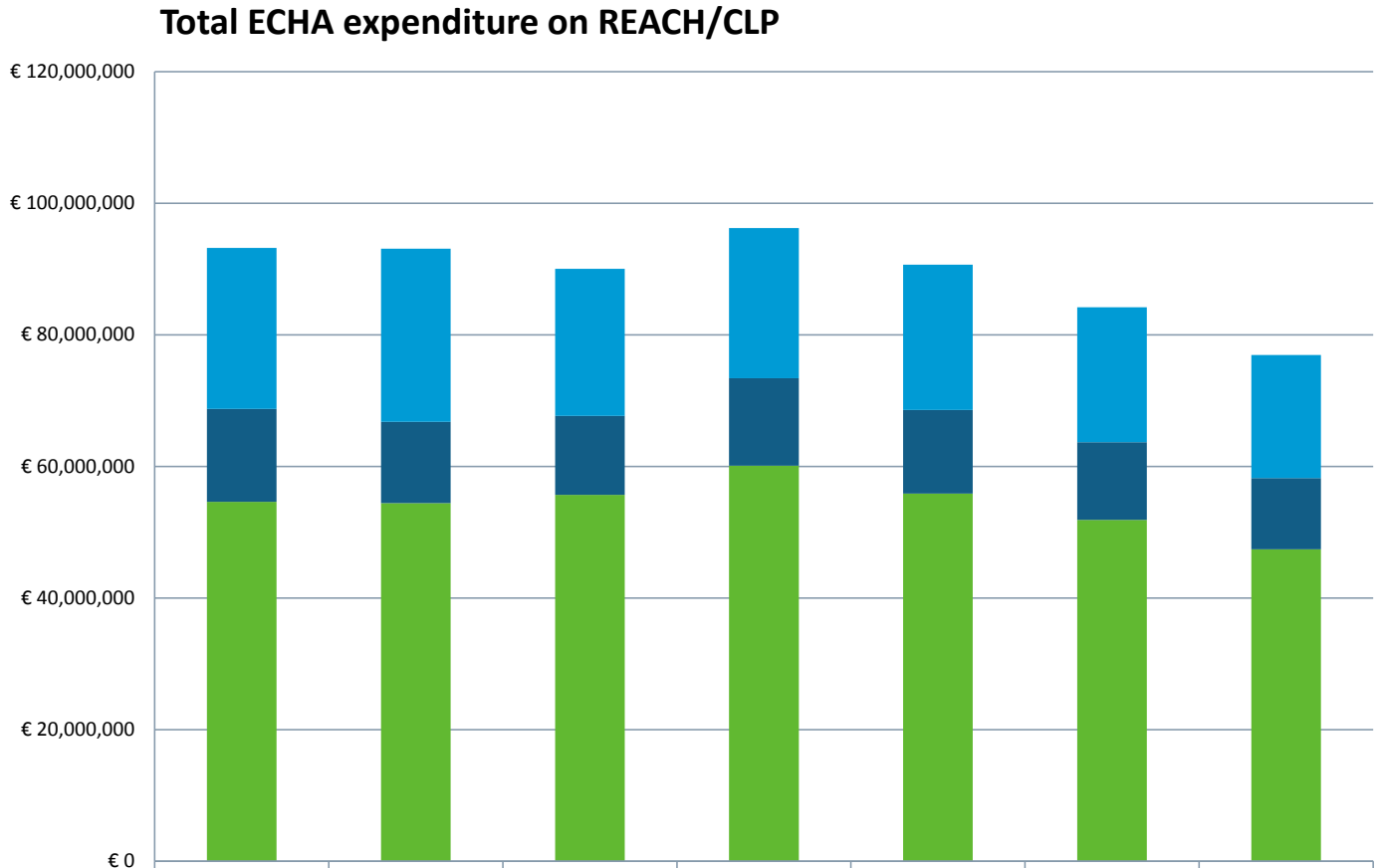
- Figure U: REACH/CLP operational expenditure - Evaluation expanded to all >1000 using higher levels of
- Figure V: Total expenditure on REACH/CLP activities - Evaluation expanded to all >1000 using higher levels of
- Figure W: Revenue from REACH/CLP fees and charges - Evaluation expanded to all >1000 using higher levels of scrutiny
- Figure X: Total revenue - Evaluation expanded to all >1000 using higher levels of scrutiny

Figure U: REACH/CLP operational expenditure - Evaluation expanded to all >1000 using higher levels of strategy applied only to lead and individual registration dossiers over 10 years



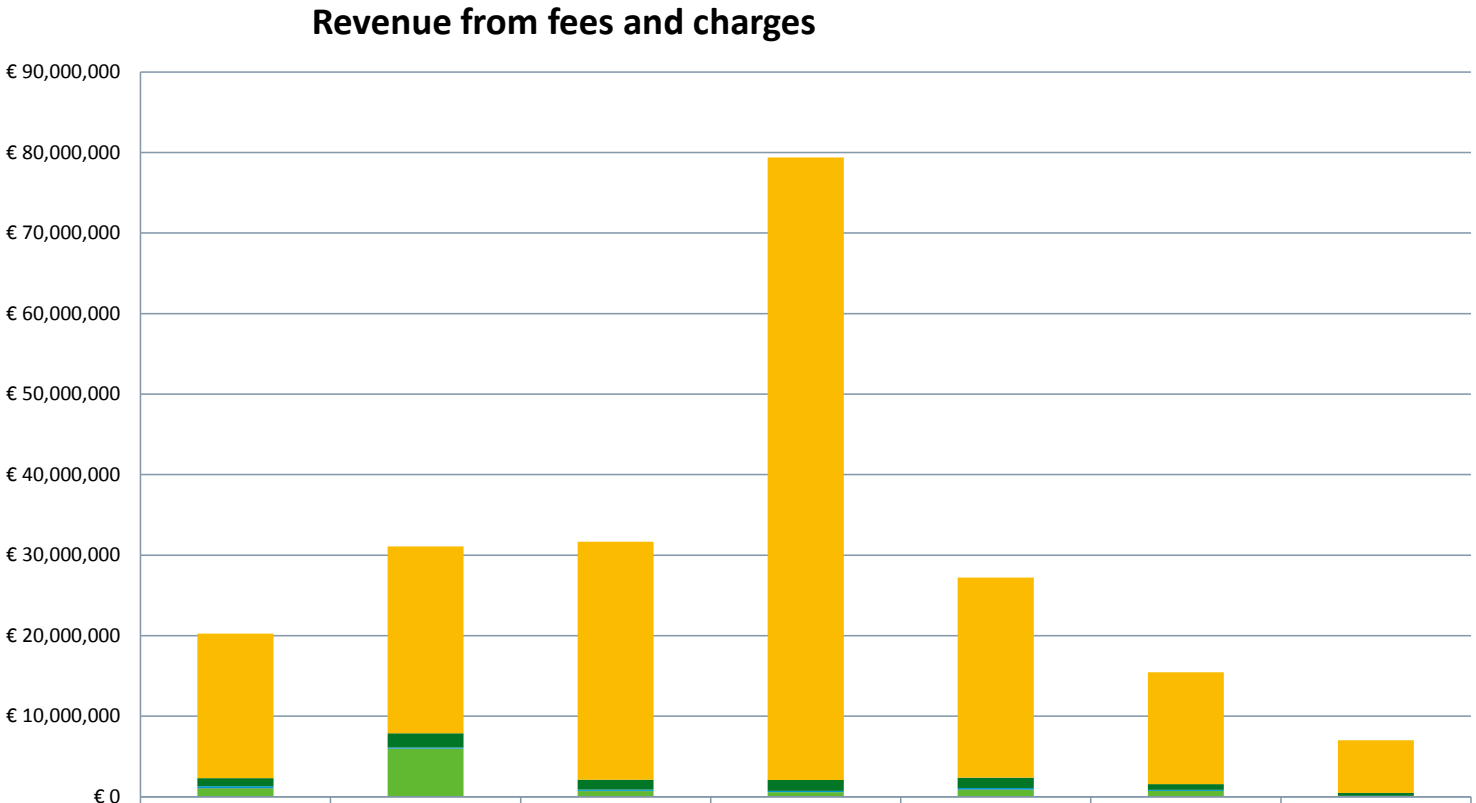
	2015	2016	2017	2018	Short	Medium	Long
Other operational activities cross cutting, international, horizontal and multi-annual reporting activities	€ 7,693,663	€ 8,912,339	€ 7,703,336	€ 6,518,624	€ 7,500,000	€ 7,500,000	€ 7,500,000
Scientific and technical advice to EU institutions and bodies	€ 188,689	€ 103,371	€ 259,000	€ 446,206	€ 200,000	€ 200,000	€ 200,000
Scientific IT tools	€ 13,704,528	€ 14,854,250	€ 11,978,562	€ 12,763,786	€ 10,000,000	€ 10,000,000	€ 10,000,000
Advice and assistance through guidance and helpdesk	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Classification and labelling	€ 154,965	€ 13,194	€ 64,218	€ 48,285	€ 67,000	€ 57,000	€ 15,000
Risk Management	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Evaluation	€ 1,654,669	€ 1,295,374	€ 195,273	€ 136,000	€ 3,016,000	€ 1,783,000	€ 689,000
Registration, datasharing and dissemination	€ 562,988	€ 533,989	€ 1,254,168	€ 1,865,491	€ 432,000	€ 240,000	€ 114,000

Figure V: Total expenditure on REACH/CLP activities - Evaluation expanded to all >1000 using higher levels of strategy applied only to lead and individual registration dossiers over 10 years



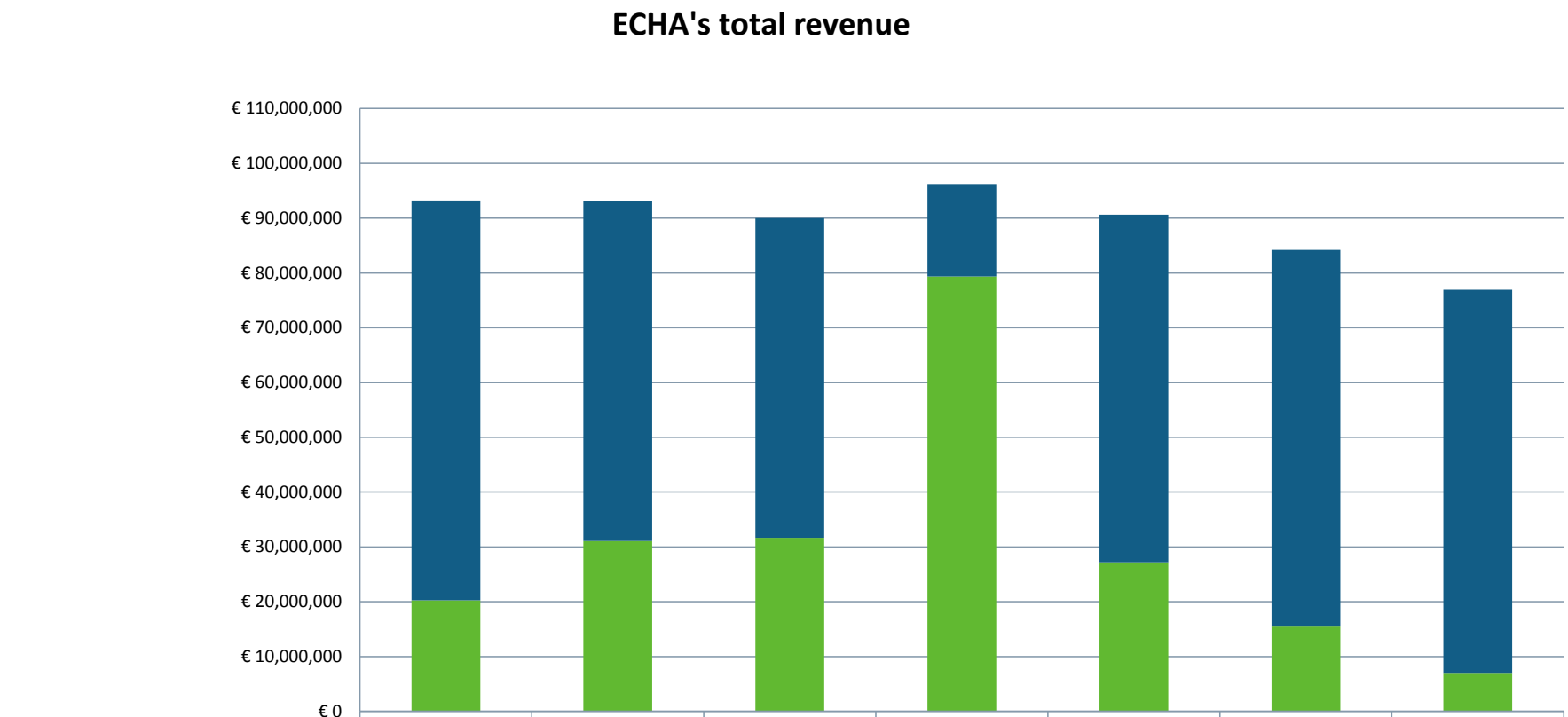
	2015	2016	2017	2018	Short	Medium	Long
REACH operating expenditure	€ 24,495,700	€ 26,309,440	€ 22,356,362	€ 22,825,148	€ 22,066,000	€ 20,494,000	€ 18,728,000
Building, equipment and miscellaneous operating expenditure	€ 14,101,605	€ 12,347,132	€ 11,983,639	€ 13,285,047	€ 12,713,000	€ 11,807,000	€ 10,790,000
Staff	€ 54,618,876	€ 54,412,542	€ 55,683,201	€ 60,121,356	€ 55,867,000	€ 51,887,000	€ 47,417,000

Figure W: Revenue from REACH/CLP fees and charges - Evaluation expanded to all >1000 using higher levels of scrutiny applied only to lead and individual registration dossiers over 10 years



	2015	2016	2017	2018	Short	Medium	Long
New sub Registration + updates + late registration	€ 17,955,000	€ 23,210,566	€ 29,553,000	€ 77,308,000	€ 24,844,000	€ 13,869,000	€ 6,567,000
Other fees and charges	€ 1,000,000	€ 1,750,000	€ 1,233,700	€ 1,357,000	€ 1,294,000	€ 722,000	€ 342,000
CLP	€ 229,000	€ 144,000	€ 148,613	€ 148,000	€ 147,000	€ 124,000	€ 34,000
Appeals	€ 7,069	€ 14,244	€ 14,315	€ 0	€ 58,000	€ 7,000	€ 3,000
Authorisation	€ 1,066,000	€ 5,961,449	€ 714,661	€ 570,077	€ 867,000	€ 728,000	€ 84,000

Figure X: Total revenue - Evaluation expanded to all >1000 using higher levels of scrutiny applied only to lead and individual registration dossiers over 10 years



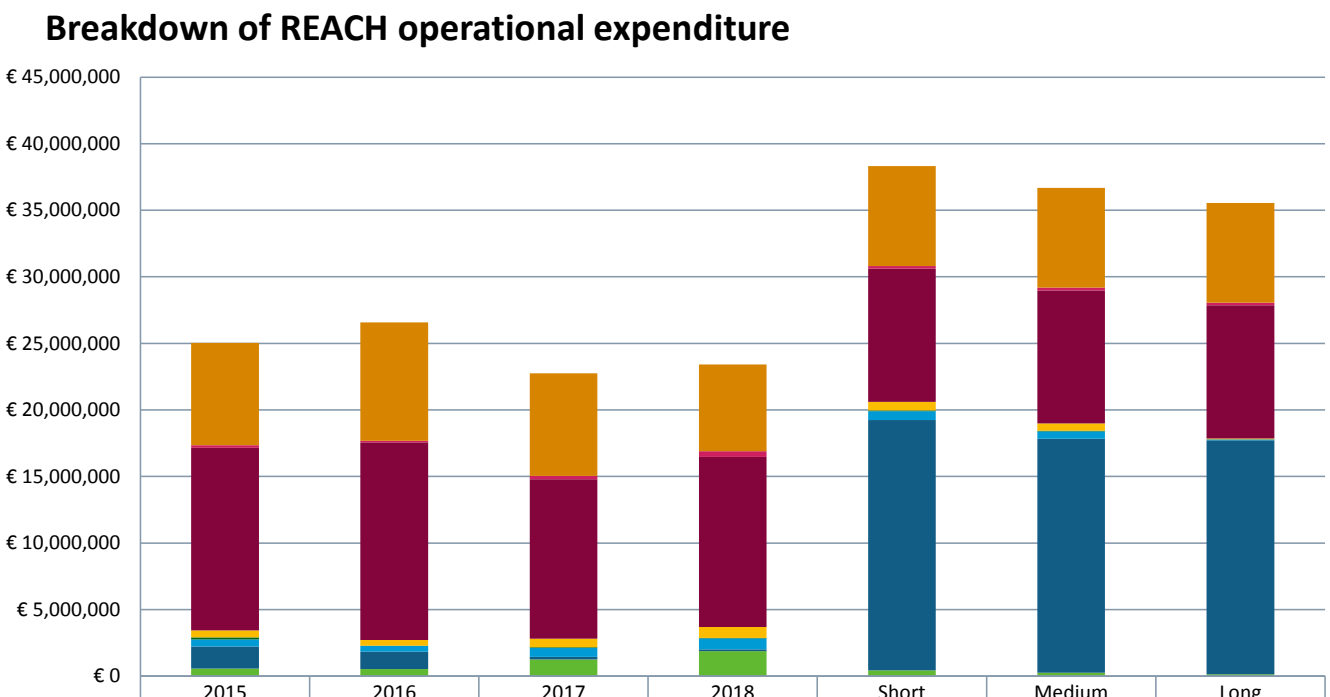
	2015	2016	2017	2018	Short	Medium	Long
Contributions from EU budgets (and EFTA)	€ 72,959,112	€ 61,988,855	€ 58,358,912	€ 16,848,474	€ 63,436,000	€ 68,738,000	€ 69,905,000
REACH/CLP fees and charges	€ 20,257,069	€ 31,080,259	€ 31,664,289	€ 79,383,077	€ 27,210,000	€ 15,450,000	€ 7,030,000

A.5 Expenditure and revenue - Evaluation expanded to all >1000 using higher levels of scrutiny applied to all dossiers (lead, member and individual) over 20 years

The following figures provide the estimates and breakdowns of expenditure and fees under this scenario:

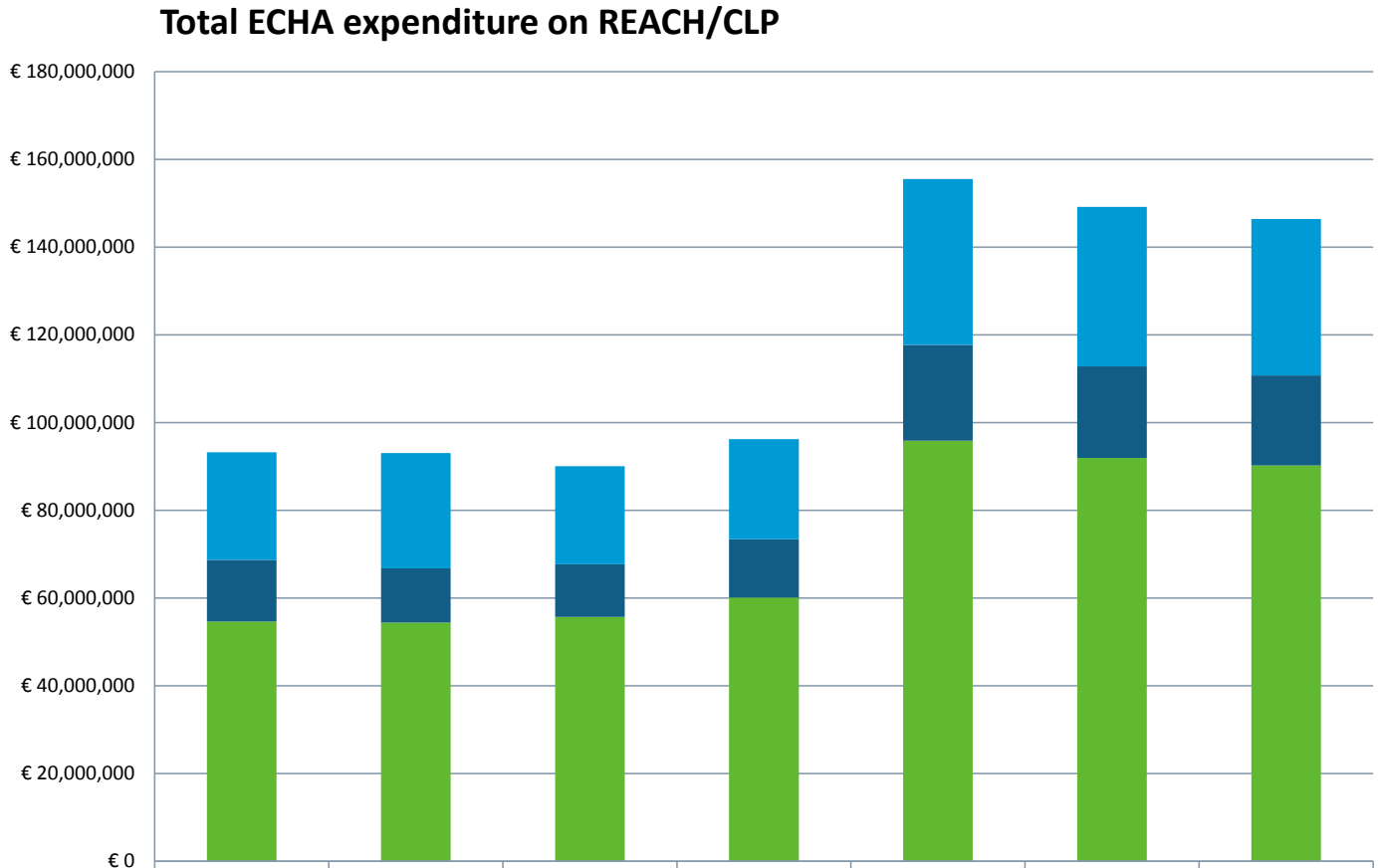
- Figure Y: REACH/CLP operational expenditure - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years
- Figure Z: Total expenditure on REACH/CLP activities - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years
- Figure AA: Revenue from REACH/CLP fees and charges - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years
- Figure BB: Total revenue - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years

Figure Y: REACH/CLP operational expenditure - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years



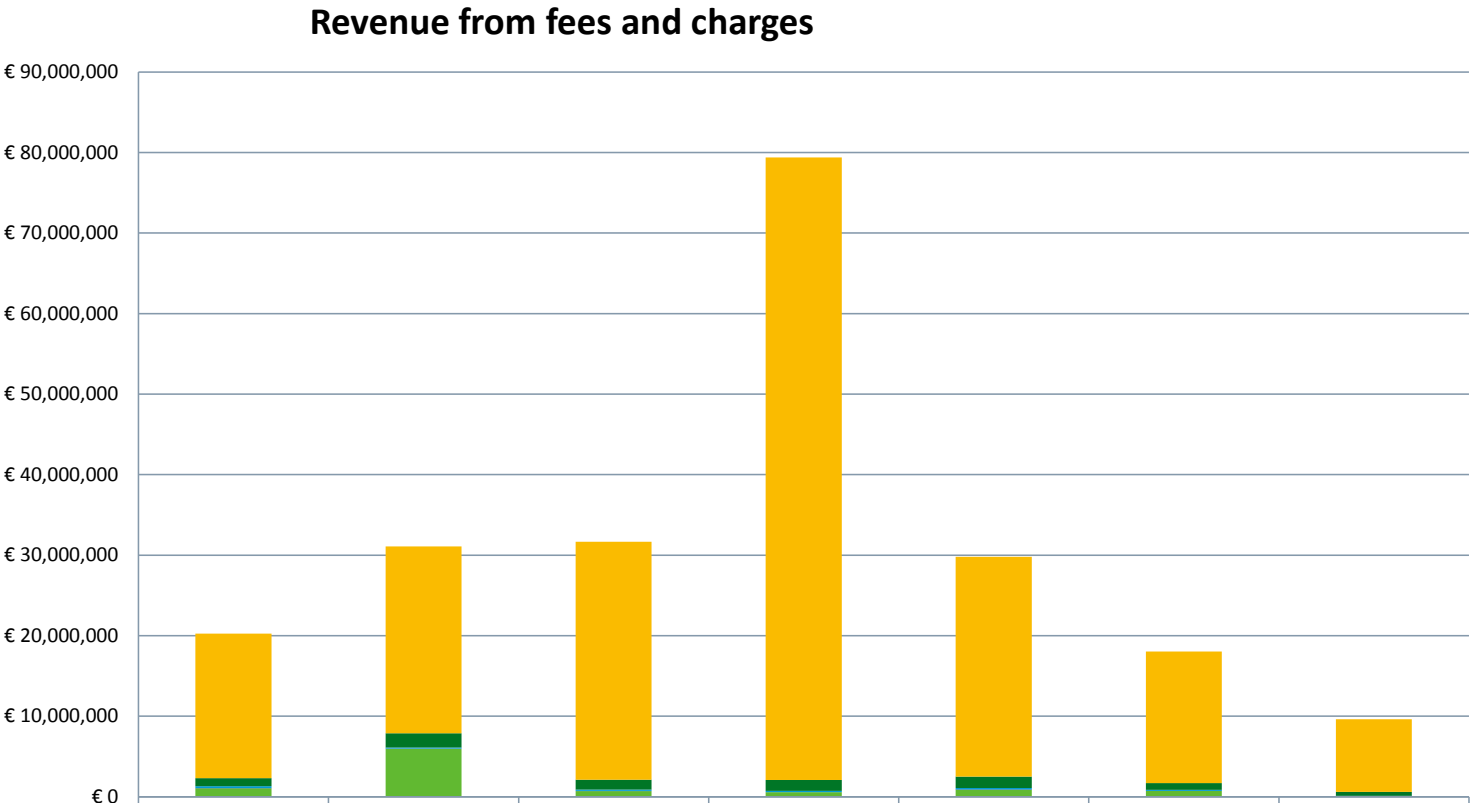
	2015	2016	2017	2018	Short	Medium	Long
Other operational activities cross cutting, international, horizontal and multi-annual reporting activities	€ 7,693,663	€ 8,912,339	€ 7,703,336	€ 6,518,624	€ 7,500,000	€ 7,500,000	€ 7,500,000
Scientific and technical advice to EU institutions and bodies	€ 188,689	€ 103,371	€ 259,000	€ 446,206	€ 200,000	€ 200,000	€ 200,000
Scientific IT tools	€ 13,704,528	€ 14,854,250	€ 11,978,562	€ 12,763,786	€ 10,000,000	€ 10,000,000	€ 10,000,000
Advice and assistance through guidance and helpdesk	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Classification and labelling	€ 154,965	€ 13,194	€ 64,218	€ 48,285	€ 67,000	€ 57,000	€ 15,000
Risk Management	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Evaluation	€ 1,654,669	€ 1,295,374	€ 195,273	€ 136,000	€ 18,806,000	€ 17,573,000	€ 17,573,000
Registration, datasharing and dissemination	€ 562,988	€ 533,989	€ 1,254,168	€ 1,865,491	€ 437,000	€ 261,000	€ 144,000

Figure Z: Total expenditure on REACH/CLP activities - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years



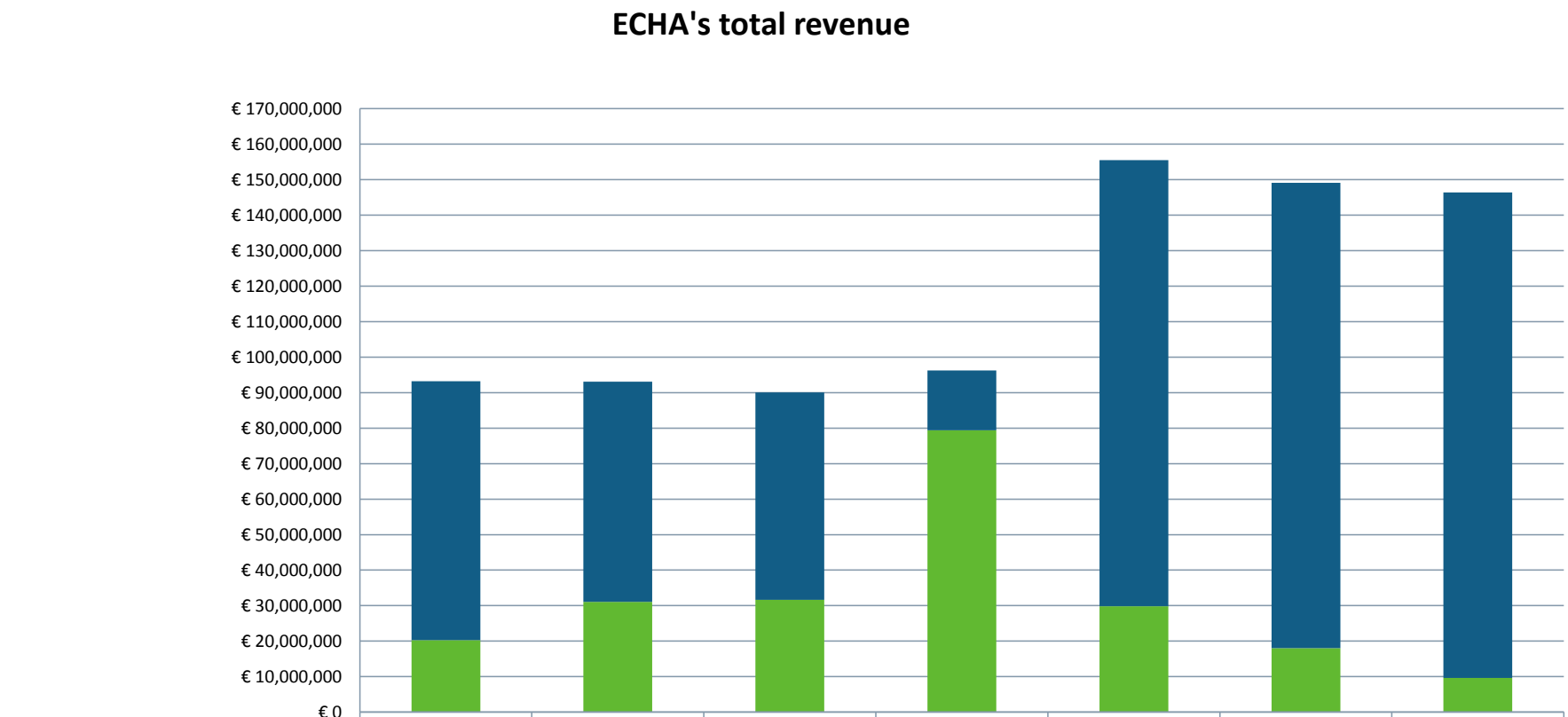
	2015	2016	2017	2018	Short	Medium	Long
REACH operating expenditure	€ 24,495,700	€ 26,309,440	€ 22,356,362	€ 22,825,148	€ 37,861,000	€ 36,305,000	€ 35,642,000
Building, equipment and miscellaneous operating expenditure	€ 14,101,605	€ 12,347,132	€ 11,983,639	€ 13,285,047	€ 21,813,000	€ 20,916,000	€ 20,534,000
Staff	€ 54,618,876	€ 54,412,542	€ 55,683,201	€ 60,121,356	€ 95,858,000	€ 91,917,000	€ 90,239,000

Figure AA: Revenue from REACH/CLP fees and charges - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years



	2015	2016	2017	2018	Short	Medium	Long
New sub Registration + updates + late registration	€ 17,955,000	€ 23,210,566	€ 29,553,000	€ 77,308,000	€ 27,309,000	€ 16,334,000	€ 9,032,000
Other fees and charges	€ 1,000,000	€ 1,750,000	€ 1,233,700	€ 1,357,000	€ 1,423,000	€ 851,000	€ 471,000
CLP	€ 229,000	€ 144,000	€ 148,613	€ 148,000	€ 147,000	€ 124,000	€ 34,000
Appeals	€ 7,069	€ 14,244	€ 14,315	€ 0	€ 63,000	€ 8,000	€ 5,000
Authorisation	€ 1,066,000	€ 5,961,449	€ 714,661	€ 570,077	€ 867,000	€ 728,000	€ 84,000

Figure BB: Total revenue - Evaluation expanded to all >1000t substances using current screening strategy applied to all dossiers (lead, member and individual) over 20 years



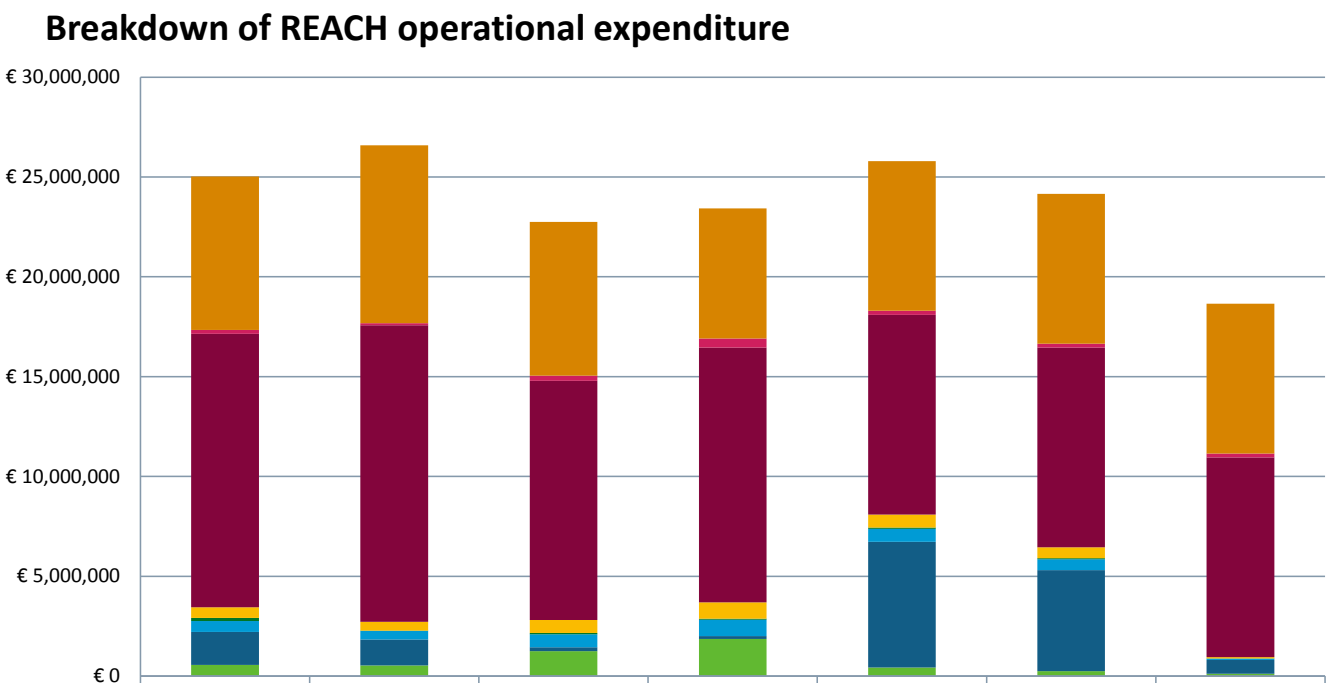
	2015	2016	2017	2018	Short	Medium	Long
Contributions from EU budgets (and EFTA)	€ 72,959,112	€ 61,988,855	€ 58,358,912	€ 16,848,474	€ 125,723,000	€ 131,093,000	€ 136,789,000
REACH/CLP fees and charges	€ 20,257,069	€ 31,080,259	€ 31,664,289	€ 79,383,077	€ 29,809,000	€ 18,045,000	€ 9,626,000

A.6 Expenditure and revenue - Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years

The following figures provide the estimates and breakdowns of expenditure and fees under this scenario:

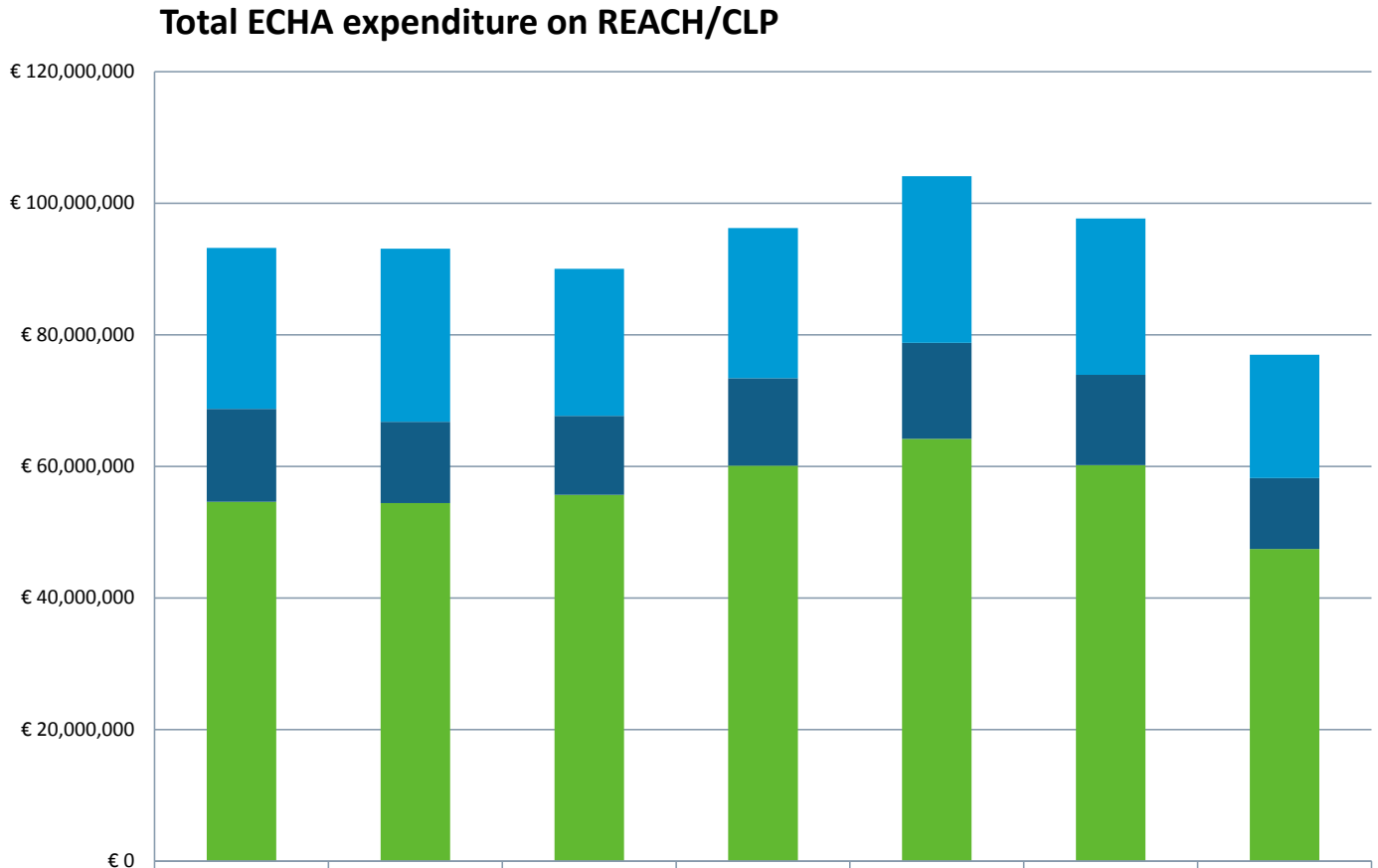
- Figure CC: REACH/CLP operational expenditure - Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years
- Figure DD: Total expenditure on REACH/CLP activities - Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years
- Figure EE: Revenue from REACH/CLP fees and charges - Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years
- Figure FF: Total revenue - Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years

Figure CC: REACH/CLP operational expenditure - Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years



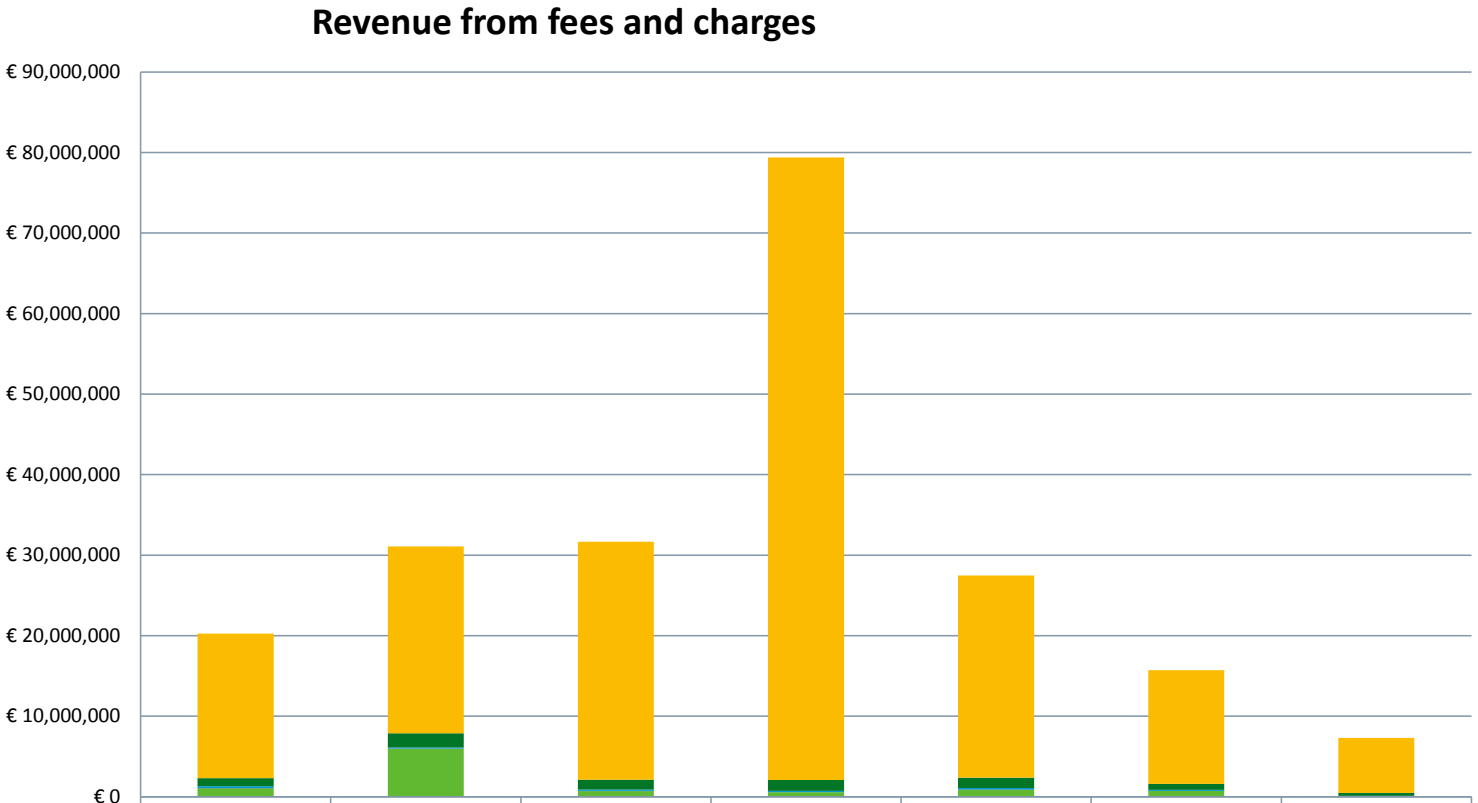
	2015	2016	2017	2018	Short	Medium	Long
Other operational activities cross cutting, international, horizontal and multi-annual reporting activities	€ 7,693,663	€ 8,912,339	€ 7,703,336	€ 6,518,624	€ 7,500,000	€ 7,500,000	€ 7,500,000
Scientific and technical advice to EU institutions and bodies	€ 188,689	€ 103,371	€ 259,000	€ 446,206	€ 200,000	€ 200,000	€ 200,000
Scientific IT tools	€ 13,704,528	€ 14,854,250	€ 11,978,562	€ 12,763,786	€ 10,000,000	€ 10,000,000	€ 10,000,000
Advice and assistance through guidance and helpdesk	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Classification and labelling	€ 154,965	€ 13,194	€ 64,218	€ 48,285	€ 67,000	€ 57,000	€ 15,000
Risk Management	€ 536,198	€ 435,522	€ 650,905	€ 822,656	€ 651,000	€ 546,000	€ 63,000
Evaluation	€ 1,654,669	€ 1,295,374	€ 195,273	€ 136,000	€ 6,296,000	€ 5,063,000	€ 689,000
Registration, datasharing and dissemination	€ 562,988	€ 533,989	€ 1,254,168	€ 1,865,491	€ 432,000	€ 244,000	€ 118,000

Figure DD: Total expenditure on REACH/CLP activities - Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years



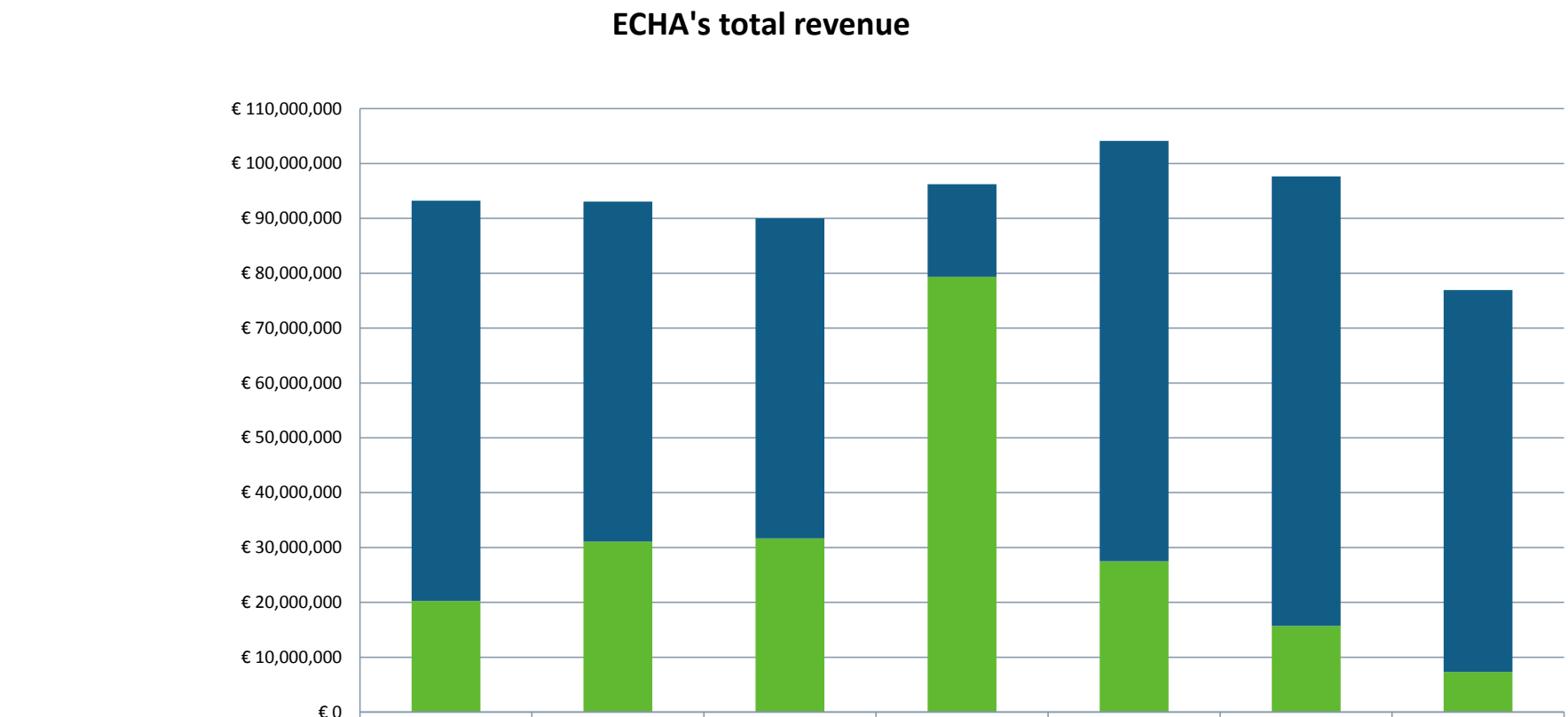
	2015	2016	2017	2018	Short	Medium	Long
REACH operating expenditure	€ 24,495,700	€ 26,309,440	€ 22,356,362	€ 22,825,148	€ 25,346,000	€ 23,778,000	€ 18,732,000
Building, equipment and miscellaneous operating expenditure	€ 14,101,605	€ 12,347,132	€ 11,983,639	€ 13,285,047	€ 14,603,000	€ 13,699,000	€ 10,792,000
Staff	€ 54,618,876	€ 54,412,542	€ 55,683,201	€ 60,121,356	€ 64,172,000	€ 60,200,000	€ 47,427,000

Figure EE: Revenue from REACH/CLP fees and charges - Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years



	2015	2016	2017	2018	Short	Medium	Long
New sub Registration + updates + late registration	€ 17,955,000	€ 23,210,566	€ 29,553,000	€ 77,308,000	€ 25,105,000	€ 14,130,000	€ 6,828,000
Other fees and charges	€ 1,000,000	€ 1,750,000	€ 1,233,700	€ 1,357,000	€ 1,308,000	€ 736,000	€ 356,000
CLP	€ 229,000	€ 144,000	€ 148,613	€ 148,000	€ 147,000	€ 124,000	€ 34,000
Appeals	€ 7,069	€ 14,244	€ 14,315	€ 0	€ 58,000	€ 7,000	€ 3,000
Authorisation	€ 1,066,000	€ 5,961,449	€ 714,661	€ 570,077	€ 867,000	€ 728,000	€ 84,000

Figure FF: Total revenue - Evaluation expanded to all >1000 using higher levels of scrutiny only to lead and individual registration dossiers over 10 years



	2015	2016	2017	2018	Short	Medium	Long
Contributions from EU budgets (and EFTA)	€ 72,959,112	€ 61,988,855	€ 58,358,912	€ 16,848,474	€ 76,636,000	€ 81,952,000	€ 69,646,000
REACH/CLP fees and charges	€ 20,257,069	€ 31,080,259	€ 31,664,289	€ 79,383,077	€ 27,485,000	€ 15,725,000	€ 7,305,000

B EU agencies and joint undertakings

B.1 Introduction

This section describes the funding models of EU agencies other than ECHA. This comprises:

- Providing an overview of the EU agencies and funding models; and
- Drawing lessons learned for the future funding of ECHA (to be further developed during the remainder of the study).

B.2 Overview of EU agencies & funding models

B.2.1 Overview of EU agencies

There are currently 46 EU decentralised agencies and joint undertakings[23] that have been created to carry out specific legal, technical or scientific tasks (EU Agencies Network, 2018[24], 2016[25]; Spagnoli, 2017[26]). Between them, these agencies and undertakings receive around 0.6% of the overall EU budget (EU Agencies Network, 2016). The 2018 Draft EU Budget (DB) recognises 33 decentralised agencies with a total budget (excluding the Single Resolution Board) of €2.5 billion, of which the EU contribution is €1.2-1.4 billion (European Parliament, 2017)[27]. The total employment in decentralised agencies is around 6,500 staff (European Parliament, 2017, Spagnolli, 2017).

The EU agencies that are most relevant to this study are listed below (only large agencies and/or those with funding models considered further in this section are listed). A full list of the 46 agencies and joint undertakings is provided at the end of this annex.

Table 9: Selected EU agencies

Acronym	Full name	Staff	2015 budget (€m)	% of EU budget	Website
CPVO	Community Plant Variety Office	45	15 (18 in 2016)	0%	http://cpvo.europa.eu
EASA	European Aviation Safety Agency	833	150 (142 in 2016)	0.022% (2016: fees and charges 96, EU subsidy 39, multiannual	https://www.easa.europa.eu

[23] EU Agencies Network (2016): EU Joint Undertakings are public-private partnerships financed partly through contributions from industry and partly from the EU budget. In 2016, their total budget was €1.36 billion (approximately one half from industry, one half from budget contributions).

[24] See https://euagencies.eu

[25] EU Agencies Network (2016): The EU Agencies, available at https://euagencies.eu/assets/files/EU_Agencies_brochure_2016.pdf

[26] Spagnolli (2017): Oversight and resources of partially and fully self-financed agencies, available at http://www.europarl.europa.eu/RegData/etudes/STUD/2017/572719/IPOL_STU(2017)572719_EN.pdf

[27] European Parliament (2017): Tender specifications, available at https://www.politico.eu/wp-content/uploads/2017/11/SPOLITICO-17111611370.pdf

Acronym	Full name	Staff	2015 budget (€m)	% of EU budget	Website
				special projects 7)	
EBA	European Banking Authority	151	33.5	0.02%	http://www.eba.europa.eu
ECDC	European Centre for Disease Prevention and Control	290	58.4	0.036%	https://ecdc.europa.eu/en/home
ECHA	European Chemicals Agency	600	107	0.003%	http://echa.europa.eu
EDA	European Defence Agency	130	30.5	0%	https://eda.europa.eu
EEA	European Environment Agency	205	41.7	0.02%	https://www.eea.europa.eu
EFSA	European Food Safety Authority	447	76.9	0.049%	http://www.efsa.europa.eu
EIOPA	European Insurance and Occupational Pensions Authority	137	20.6	0.0127%	https://eiopa.europa.eu
EMA	European Medicines Agency	890	304.1	Close to 0%	http://www.ema.europa.eu/ema/
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction	100	15.3	0.0094%	http://www.emcdda.europa.eu
EMSA	European Maritime Safety Agency	207	54.2	0.03%	http://www.emsa.europa.eu
ESMA	European Securities and Markets Authority	194	39.4	0.002%	https://www.esma.europa.eu
ETF	European Training Foundation	130	20.1	0.01%	http://www.etf.europa.eu
EU-LISA	European Agency for the operational management of large-scale IT systems in the area of freedom, security and justice	140	67.6	0.04%	https://www.eulisa.europa.eu/Pages/default.aspx
EUIPO (formerly OHIM)	European Union Intellectual Property Office	793	384.2	0%	http://euipo.europa.eu
ERA	European Union Agency for Railways	160	24.7	0.015%	http://www.era.europa.eu

Acronym	Full name	Staff	2015 budget (€m)	% of EU budget	Website
FRA	European Union Agency for Fundamental Rights	107	21.6	0.013%	http://fra.europa.eu/en
GSA	European Global Navigation Satellite Systems Agency	140	27.6	0.02%	http://www.gsa.europa.eu
SatCen	European Union Satellite Centre	120	17.9	0.0013%	https://www.satcen.europa.eu
SRB	Single Resolution Board	164	22	0%	https://srb.europa.eu
Sources: EU Agencies (2016), https://euagencies.eu, Ekvad (2017), Mastio (2017), Deloitte (2013)					

B.2.2 Overview of the funding models

The European Parliament (2017)[28] notes that the majority of EU agencies are funded entirely by contributions from the EU budget. Some agencies are, however, fully or partially dependent on other sources of income, e.g. industry fees and charges or contributions from national authorities (both in the EU and outside the EU). The classification of the agencies that are not fully funded from the EU budget is reproduced below; these are seen as most relevant to this study, since (like ECHA) they rely (at least partially) on sources of income other than the EU budget. The European Food Safety Authority (EFSA) is treated as fully funded for the purposes of this study although a minor part of its revenue comprises contributions from EEA/EFTA countries.

Table 10: Decentralised EU agencies not fully funded from the EU budget

Type	Agencies
Fully self-financed agencies	European Union Intellectual Property Office (EUIPO) Community Plant Variety Office (CPVO) Single Resolution Board (SRB) Translation Centre for the Bodies of the European Union (CdT)
Partially self-financed agencies	European Chemicals Agency (ECHA) (ECHA-REACH, ECHA-PIC, ECHA-Biocides) European Aviation Safety Agency (EASA) European Medicines Agency (EMA)
Agencies fully funded or partially co-financed by national public authorities	European Banking Authority (EBA) European Defence Agency (EDA) European Insurance and Occupational Pensions Authority (EIOPA)[29] European Securities and Markets Authority (ESMA)[30]

[28] European Parliament (2017): Tender specifications, available at https://www.politico.eu/wp-content/uploads/2017/11/SPOLITICO-17111611370.pdf

[29] 60% Contributions by Member States. 40% EU funds

[30] Malan et al (2016): ESMA: 38% of funding from national competent authorities and 26% from the fees from the private sector.

Type	Agencies
	EU Satellite Centre (SatCen)[31]

Sources: Ekvad (2017), European Parliament (2017), Presa (2017) , own research

The table above suggests that the agencies that are most similar to ECHA with regard to their financing are EASA and EMA since both combine fee income with contributions from the EU budget, i.e. they are partially self-funded. This report therefore provides most detail on these two agencies.

Kapff et al (2014)[32] has identified two approaches to cost/fee determination and the treatment of surpluses/deficits in partially self-financed EU agencies[33]:

- the assigned revenue model (EASA); and
- the universal budgeting model (ECHA and EMA).

Please note that the scope of Kapff et al (2014) only includes agencies whose revenue streams include both fees from industry and subsidies from the EU budget and that are not co-financed by national authorities (i.e. EASA, ECHA and EMA). The agencies excluded from the scope of Kapff et al (2014) are fully self-financed EU agencies (CdT, CPVO, OHIM) and agencies fully or partially co-financed by national authorities (EBA, EDA, EIOPA, ESMA, SatCen). It is noted that ESMA also receives fees from industry.

The key features of these approaches are summarised in the table below.

Table 11: Assigned revenue vs universal budgeting model

Feature	Assigned revenue model	Feature
Key characteristics	• **Strict separation** between fee revenue and contributions from the EU budget • **No cross-subsidisation**: fee revenue used for provision of industry services, EU budget contribution used for public tasks	• **Universality** of the Financial Regulation (total budget revenue to cover total expenditure) • **Cross-subsidisation** is possible
Fee determination	• Objective: **recover full costs** of services to industry from industry (long-term considerations)	• Fees determined on cost and other **policy considerations**
Surpluses/deficits	• Due to volatility of fee income, **surpluses/deficits can occur** • **Reserve fund** required to deal with volatility	• **Balancing subsidy principle** of the Financial Regulation: Surpluses to be repaid to the EU budget (in the following year),

[31] The budget mainly (70%) consists of Member States' contributions. https://www.satcen.europa.eu/key_documents/EU%20SatCen%20Annual%20Report%20201658e24cb1f9d7202538bed52b.pdf

[32] Kapff et al (2014): Partially self-financed EU Agencies and the principle of fee setting, available at http://www.europarl.europa.eu/RegData/etudes/etudes/join/2014/490689/IPOL-JOIN_ET(2014)490689_EN.pdf

[33] Partially self-financed EU agencies: agencies which carry out public tasks for the EU and provide services to clients from industry and are not co-financed by national public authorities. This definition excluded joint undertakings and agencies funded by Member State contributions (e.g. EDA).

Feature	Assigned revenue model	Feature
	• Need for stability encourages renewal fees	up to the level of the total EU subsidy paid. • Deficits are covered by additional transfers and/or an amending budget
Accounting & transparency	• Activity-based accounting (separation required) • **Regular information provision** to users on cost structure	• No assignment of revenue • **No specific cost information obligations** vis-à-vis their users
Consequences	• Strict accounting separation • No indirect taxation • Transparency • Need for a reserve fund	• Budgetary flexibility • Potential for indirect taxation • Limited transparency • EU budget absorbs volatility • Administratively lighter
Source: Kapff et al (2014), Presa (2017)[34]		

A prerequisite for **charging fees to industry** is the provision of services to, or surveillance of, industry. It is also of note that there are currently six EU agencies which are providing services to industry but not charging fees (European Parliament, 2017):

- Agency for the Cooperation of Energy Regulators (ACER);
- European Banking Authority (EBA);
- European Food Safety Authority (EFSA);
- European Insurance and Occupational Pensions Authority (EIOPA);
- European Maritime Safety Agency (EMSA); and
- European Railway Agency (ERA).

However, as noted in European Parliament (2017), EBA and EIOPA are co-funded by Member States and charges can be levied on the industry at the Member State level.

There are ongoing discussions about the extension of the practice of charging fees to other EU agencies (e.g. EFSA) and a study on this issue[35] for the Budget Committee of the European Parliament is scheduled to be finalised soon.

With regard to **charging Member States**, agencies can charge for additional services (not for their core tasks) such as the provision of operational information, data, publications, expertise, consultative support, and training, etc. The following are examples of agencies charging Member States for the provision of services (European Parliament, 2017):

- EASA for training; and
- EMSA for data services, e.g. satellite images for shipping.

[34] Presa (2017): Oversight and resources of partially and fully self-financed EU agencies, available at http://www.europarl.europa.eu/RegData/etudes/STUD/2017/572719/IPOL_STU(2017)572719_EN.pdf

[35] Study "Potential revenue from the extension of charging fees by EU Agencies"

With respect to the legal position, both models are allowed by the Financial Regulation (Articles 20 and 21, pp.61-65).[36] The Framework Financial Regulation[37] foresees that, in general, fee funded activities are not separated from Union-funded activities, unless this is explicitly stated in the agency's basic act (Kapff et al, 2014).

As regards operating principles, the European Commission/Council/Parliament (2012) Joint Statement[38] notes (with regard to partially self-financed agencies) that:

> *The clients should pay the full cost of the services provided to them by those agencies, including the employer's prorate contribution to the pension scheme. Concerning the issue of how to deal with a possible shortfall against forecast of fee revenue from the clients and the need to ensure the availability of necessary funding to agencies, the Commission will investigate the necessity and possible modalities of creating a limited ring-fenced reserve fund to be operated in a transparent way.*

B.2.3 Extend of self-financing

Malan et al (2016)[39] examined seven partially or fully self-funded agencies: the European Union Intellectual Property Office (EUIPO), European Aviation Safety Agency (EASA), European Medicines Agency (EMA), European Chemicals Agency (ECHA), European Banking Authority (EBA), European Securities and Markets Authority (ESMA), and the European Insurance & Occupational Pensions Authority (EIOPA). In 2015, the cost of operating the seven agencies was € 1 billion (of which €80 million was funded through the EU budget). Over 90% of these agencies' expenditure thus came from fees and charges. EUIPO and CPVO do not rely on EU funding at all. EASA, EBA, ESMA and EIOPA are highly dependent on grants while EMA and ECHA are less dependent.

Table 12: Decentralised EU agencies not fully funded from the EU budget

Agency	EU subsidy (% of overall agency budget in 2015)
CPVO, EUIPO	0%
EASA	30%
EMA	1%
EBA	40%[40]
ESMA	30%
EIOPA	40%

Source: Malan et al (2016)

[36] EU Financial Regulation 2017, available at http://ec.europa.eu/budget/library/biblio/documents/regulations/financial_regulation_2017_en.pdf

[37] Commission Delegated Regulation (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council, available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R1271

[38] European Commission/Council/Parliament (2012) Joint Statement, available at https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

[39] Malan et al (2016): The Cost of Non-Agencies with Relevance to the Internal Market, available at http://www.europarl.europa.eu/RegData/etudes/STUD/2016/572702/IPOL_STU(2016)572702_EN.pdf

[40] Malan et al (2016): 60% of EBA's 2015 budget was funded by contributions from national supervisory authorities, there are no fees/charges paid by the private sector.

Around 70% of both EASA's and EMA's income is from fees, so they are largely self-funding (PwC, 2012)[41].

B.2.4 Future evolution of funding and cost saving of agencies

Potential future developments include:

- **Pressures on the EU budget contribution, reduced expenditure and potential for increased charging of fees**: the overall EU budget contribution is expected to remain broadly constant over the current financial framework period (2014-2020) and there has been pressure to reduce the number of staff (with a target of 5% staff reduction) (Ekvad, 2017; Presa, 2017, Spagnolli, 2017);
- **Measures to improve fee income predictability**: for example, EASA is currently running a pilot to identify indicators to adapt resources to market demand with a potential introduction of a bandwidth outside which the number of posts is adapted: for workload variations between -2% and +2% (Mastio, 2017; Presa, 2017);
- **Increased coordination/networking between agencies** within the framework of the EU Agencies Network[42] and any subgroups, e.g. the European Fee-Receiving Agencies Network (EFRAN)[43]. Spagnolli (2017) notes that EU agencies resource and governance in the future could include:
  - Sharing of services and capabilities
  - Performance focus
  - Sectorial/thematic approach
  - Simpler and flexible financial and staff rules
  - Collaboration and dialogue between institutions

B.3 Examples of funding models

B.3.1 European Aviation Safety Agency (EASA)

The tasks carried out by EASA[44] include:

- Draft implementing rules in all fields pertinent to the EASA mission

[41] PwC (2012): The impact on the EU and national budgets of EU agencies - case studies, available at http://www.europarl.europa.eu/RegData/etudes/etudes/join/2012/453235/IPOL-JOIN_ET(2012)453235_EN.pdf

[42] See https://euagencies.eu/

[43] EFSA (2017): 2017-2018 Work Programme of the Network of EU Agencies Under the Chairmanship of EFSA, available at https://www.efsa.europa.eu/sites/default/files/170324-0-agencies_work_programme.pdf

[44] See https://www.easa.europa.eu/the-agency/the-agency

- Certify and approve products and organisations, in fields where EASA has exclusive competence (e.g. airworthiness)
- Provide oversight and support to Member States in fields where EASA has shared competence (e.g. Air Operations , Air Traffic Management)
- Promote the use of European and worldwide standards
- Cooperate with international actors in order to achieve the highest safety level for EU citizens globally (e.g. EU safety list, Third Country Operators authorisations)

Article 59 of Regulation 216/2008[45] requires separation of industry and public activities of EASA and defines the sources of funding:

> *Regulatory budgets and the fees set and collected for certification activities shall be dealt with separately in the Agency's budget.*
>
> *The revenues of the Agency shall consist of: (a) a contribution from the Community; (b) a contribution from any European third country with which the Community has concluded agreements […]; (c) the fees paid by applicants for, and holders of, certificates and approvals issued by the Agency; (d) charges for publications, training and any other services provided by the Agency; and (e) any voluntary financial contribution from Member States, third countries or other entities, provided such a contribution does not compromise the independence and impartiality of the Agency. The expenditure of the Agency shall include staff, administrative, infrastructure and operational expenses.*

Article 16 of the Commission Regulation (EU) No 319/2014 (the EASA fee regulation) stipulates that in order to distinguish revenue and expenditure attributable to certification tasks and other services:

> *(a) the fees and charges levied by the Agency shall be kept in a separate account and shall be the subject of a separate accounting procedure;*
> *(b) the Agency shall draw up and use analytical accounting for its revenue and expenditure.*
> *2. The fees and charges shall be subject of an overall provisional estimate by the beginning of each financial year. This estimate shall be based on the Agency's previous financial results, its estimate of expenditure and revenue and its forward working plan.*
>
> *3. If at the end of a financial year the overall revenue from fees, which constitute an assigned revenue in accordance with Article 64(5) of Regulation (EC) No 216/2008, exceeds the overall cost of certification tasks, the excess shall be used to finance certification tasks in accordance with Article 19(1)(a) of the Agency's Financial Regulation.*

Commission Regulation (EU) No 319/2014 (the EASA fee regulation):

> *Recital 11: The industry should enjoy* ***good financial visibility and be able to anticipate the cost of the fees and charges it will be required to pay****. At the same time, it is necessary to ensure a balance between overall expenditure incurred by the Agency in carrying out certification tasks and services provided, and overall income from the fees and*

[45] Regulation (EC) No 216/2008, as amended. Consolidated version including amendments: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02008R0216-20160126

charges it levies. In accordance with provisions of the Framework Financial Regulation (3), fees and charges should be set at the level such to avoid a deficit or a significant accumulation of surplus. ***It should therefore be mandatory to review the levels of fees and charges if a significant deficit or surplus becomes recurrent on the basis of the Agency's financial results and forecasts.***

Recital 12: ***Interested parties should be consulted prior to any change of fees****. Moreover, the Agency should regularly provide interested parties with information on how and on what basis the fees are calculated. Such information should provide interested parties with an insight into the costs incurred by the Agency and its productivity.*

The following table provides a breakdown of the EASA's budget for 2016. It shows that, in 2016, 70% of the EASA's total budget (of €128.3 million) came from fees. In the previous year (2015), 68% of EASA's budget came from fees, 8% from third countries and 24% from the EU budget (Malan et al, 2016). This is similar to ECHA's current income structure but, unlike in ECHA's case, it can be expected that this is a sustainable income stream. It should be remembered that income from fees covers 100% of EASA's industry services and it is not used for any other purpose.

Table 13: EASA's budget in 2016

	(€)	%
Fees and charges	€90 million	70%
General budget	€36.3 million	28%
EEA/EFTA	€2 million	2%

Source: UK Parliament (undated): https://publications.parliament.uk/pa/cm201617/cmselect/cmfaff/1077/107709.htm

As indicated above, the EASA operates an assigned revenue model. According to Kapff et al (2014), around 25% of EASA's certification activities (which could be regarded as structurally comparable to the dossier evaluation) are subcontracted to National Aviation Authorities through competitive public procurement calls; these calls are also open to commercial entities.

The advantages of EASA's financing model is a high degree of transparency for the industry and a high degree of predictability about future income. The disadvantage is that there needs to be certainty that the industry (as a whole) can bear the full cost of the services provided.

B.3.2 European Medicines Agency (EMA)

The tasks carried out by EMA include[46]:

- Facilitating development and access to medicines including
  - support for early access;

[46] See http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000091.jsp&mid=WC0b01ac0580028a42

- scientific advice and protocol assistance;
- paediatric procedures;
- scientific support for advanced-therapy medicines;
- orphan designation of medicines for rare diseases;
- scientific guidelines on requirements for the quality, safety and efficacy testing of medicines;
- the Innovation Task Force, a forum for early dialogue with applicants; and
- Support for research and innovation in the pharmaceutical sector, and promotion of innovation and development of new medicines by European micro-, small- and medium-sized-enterprises.

► Evaluating applications for marketing authorisation

► Monitoring the safety of medicines across their lifecycle

- developing guidelines and setting standards;
- coordinating the monitoring of pharmaceutical companies' compliance with their pharmacovigilance obligations;
- contributing to international pharmacovigilance activities with authorities outside the EU; and
- informing the public on the safety of medicines and cooperating with external parties, in particular representatives of patients and healthcare professionals.

► Providing information to healthcare professionals and patients

The task structure of EMA is very similar to that of ECHA and covers a similarly complex topic as industrial chemicals.

For 2018, the total budget of the EMA is €337.8 million. Around 90% of the Agency's budget derives from fees and charges, 7% from the EU's budget for public-health issues and 3% from other sources (EMA, 2018).[47]

Articles 67-70 (Financial Provisions) of Regulation (EC) 726/2004[48] stipulate, amongst other things, that:

> *"the Agency's revenue shall consist of a contribution from the Union and fees paid by undertakings for obtaining and maintaining Union marketing authorisations and for other services provided by the Agency, or by the coordination group as regards the fulfilment of*

[47] EMA (2018): Funding, available at: http://www.ema.europa.eu/ema/:www.hma.eu/pages/includes/document/index.jsp?curl=pages/about_us/general/general_content_000130.jsp&mid=WC0b01ac0580029336

[48] Consolidated version: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02004R0726-20130605

its tasks in accordance with Articles 107c, 107e, 107g, 107k and 107q of Directive 2001/83/EC."

Other relevant legislation includes the EMA fee regulation[49] and the pharmacovigilance fee Regulation (Regulation (EU) No 658/2014).

A notable specificity of EMA is that it transfers 50% of its fee income to national competent authorities within flat rate arrangements - this is not an 'actual cost of service arrangement'. Kapff et al (2013) notes that national competent authorities (NCAs) carry out both fee-rated activities and non-fee based (i.e. non-remunerated) activities for the EMA and there is cross-subsidisation between the two areas. Since clear cost information is not provided by NCAs, EMA is unable to provide full transparency to the industry on how fee-based revenue has been spent. Note that, in 2018, an estimated €127.6 million will be paid to the national medicines regulatory agencies from the EMA's budget (EMA, 2018).[50]

In terms of the funding model and subject area, EMA seems to be the agency that is most similar to ECHA of the agencies considered in this report. However, unlike ECHA, much of EMA's services for the industry are subcontracted to NCAs within arrangements that do not provide transparency to the industry.

B.3.3 Community Plant Variety Office (CPVO)

The CPVO is a fully self-funded agency. Ekvad (2017)[51] notes that the CPVO aims for a balanced budget and where reserves are accumulated, these are managed through fee reductions (not discretionary funding); see below for CPVO spending, income and reserves.

It has been indicated that in 2015, the CPVO had a budget of €12.8 million[52]

B.3.4 ECHA's work on biocides

Starting from 2012, ECHA was charged with the additional task of managing the technical, scientific, and administrative aspects of the Biocidal Products Regulation (BPR) in order to provide Industry and Member State Authorities with technical and scientific guidance. ECHA's Biocidal Products expenditure is financed to a large extent from EU subsidies and fee-generated income from the Industry. The following paragraph intends to illustrates the sources of income ECHA receives to perform its functions in relation to BPR.

The Agency commenced invoicing of applicants under the Biocidal Products Regulation (EU) No.528/2012 from 01 September 2013. Looking at the latest Final Annual Accounts (2017), the

[49] Council Regulation (EC) No 297/95, available here: https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1526898791520&uri=CELEX:31995R0297

[50] EMA (2018): Funding, available at: http://www.ema.europa.eu/ema/;www.hma.eu/pages/includes/document/index.jsp?curl=pages/about_us/general/general_content_000130.jsp&mid=WC0b01ac0580029336

[51] Ekvad (2017): Oversight and resources of partially and fully self-funded agencies, the CPVO perspective, available at http://www.europarl.europa.eu/RegData/etudes/STUD/2017/572719/IPOL_STU(2017)572719_EN.pdf

[52] UK Parliament (undated): Appendix 2: Submission by Professor Kenneth Armstrong, University of Cambridge, available at: https://publications.parliament.uk/pa/cm201617/cmselect/cmfaff/1077/107709.htm

total value of exchange revenue accruing to ECHA from Biocide fees and charges to the Industry is as high as € 4 484 933.

The total value of fee income receivables from Biocidal Products amounts to € 501,800, compared to € 3,773,018 from REACH Products. The provision for bad debts, also known as the allowance for bad debts, allowance for doubtful accounts, or allowance for uncollectable accounts, is a reserve against the future recognition of certain accounts receivable as being uncollectible. No fee debt provision is related to Biocidal Products for the financial years 2016 and 2017, contrary to REACH Authorisation Products for which there was a provision for bad debts of more than € 2 million euros, for both the financial years 2016 and 2017.

Deferred income refers to revenues from fees and charges not earned yet as the Agency has still to complete a portion of the work. For Biocidal Product the total deferred income at the end of the financial year 2017 amounts to € 11,235,827.

In addition to the fees and charges from the Industry, the Agency relies on sources of non-exchange revenue. It annually receives EU subsidy; as an example, during 2017, the Agency obtained EU subsidy of € 69 343 068 for the implementation of the REACH, Biocidal Products and PIC Regulations. The amounts received for each of the regulations were respectively € 64 289 500, € 3 867 798 and € 1 185 770.

On top of EU subsidy, under the REACH and Biocidal Products Regulation, the Agency relies on other sources of non-exchange revenues. EFTA (European Free Trade Association) contributed € 1 623 765, € 1 587 950 and € 35 815 respectively for REACH and Biocidal Products, while Switzerland contributed with as much as € 147 341 in total for both Regulations.

The table below intends to summarise the data highlighted in this section.

Table 14: Comparison of ECHA's funding for REACH and Biocidal Products

Details	REACH Authorisation	Biocidal Products
Total exchange revenue	€ 35 176 758	€ 4 484 933
Exchange receivables, fees and charges	€ 3 773 018	€ 501 800
Fee bad debt provision	€ 2 795 827	0
Deferred income, fees and charges	€ 226 273	€ 11 235 827
EU subsidy	€ 64 289 500	€ 3 867 798
EFTA contribution	€ 1 587 950	€ 35 815
Switzerland contribution	€ 147 341	

B.4 Fee determination

Fee determination is governed by the Financial Regulation and basic acts of the agencies. The general principles of fee determination (based on Commission documents and the FFR -

Commission Delegated Regulation (EU) No 1271/2013[53] as summarised in Kapff et al 2014) include:

- **Full cost recovery:** recover the agency's work for the industry whereas the EU balancing contribution should be based to finance other activities
- **Transparency** on how fees are set
- **Balanced budgets:** Article 19 of the FFR: For bodies for which the revenue is constituted by fees and charges in addition to the Union contribution, fees should be set at a level such as to avoid a significant accumulation of surplus. Where a significant positive or negative budget result, within the meaning of Article 97, becomes recurrent, the level of the fees and charges shall be revised.
- **Informed decisions:** Article 67 of the FFR: Where the Union body collects fees and charges referred to in Article 6(1)(a), an overall provisional estimate of such fees and charges shall be made at the beginning of each financial year.

The consequences of the two models (universal budgeting vs assigned revenue) as defined in Kapff et al (2014) are:

- Assigned revenue model – full cost of service taken into account in fee determination and there is a need to ensure long-term sustainability, typically involving periodic renewal fees
- Universal budgeting model – fees based on costs and other policy considerations, e.g. financial burden on industry

The different agencies rely on different fee models, which can include flat fees, variable fees, annual fees, etc. For example, the fees charged by EASA (as defined in the EASA Fee Regulation Commission Regulation (EU) 319/2014[54]) consist of a combination of a flat fee and a variable amount that reflects the actual workload.

The flat fee also relates to the number of staff plus technical complexity – in this way, significant reductions for SMEs are achieved[55], based on the principle of taking into account "the ability of small undertakings to pay" as in Recital 4 of the EASA fee regulation (Commission Regulation (EU) 319/2014)[56].

Similarly, EMA relies on a combination of different fee types and includes:

> *fees for applications for marketing authorisation, and for variations and other changes to marketing authorisations, as well as annual fees for authorised medicines.*

[53] See https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R1271

[54] See https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32014R0319

[55] See http://www.ema.europa.eu/docs/en_GB/document_library/Other/2018/03/WC500246428.pdf

[56] See https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32014R0319

B.5 Budget deficits/surpluses

According to Kapff et al (2014):

- Assigned revenue model: surpluses and deficits dealt with by means of a reserve fund. EASA has a reserve fund – the possibility of a surplus only relates to fee-funded activities, public service activities funded from the EU budget so balancing subsidy principle applies.
- Universal budgeting model: surpluses and deficits dealt with by means of the 'balancing subsidy principle': surpluses have to be repaid to the EU budget in the following year[57] (up to the level of the total EU subsidy paid), deficits are covered by an additional transfer.

In practice, EU agencies often hold a reserve fund. In at least one case (OHIM/EUIPO) a significant surplus was accumulated in addition to the reserve fund. OHIM now EUIPO had a huge surplus (the total surplus+reserve fund was €500 million[58] whilst the annual expenditure of the agency was around €200 million – see Deloitte 2013[59]). Initially, OHIM attempted to reduce the surplus by reducing fees but this was not sufficient. A recent reform of OHIM into EUIPO thus included:

> *investing approximately €200 million in modernising itself and in helping to modernise the EU IP offices through the Cooperation Fund, in taking on new competencies (such as the Observatory) and building the appropriate organisational structures and capabilities to carry them out, and in the Convergence Programme, designed to benefit the users of the IP system everywhere in Europe.*[60]

This resulted in a decline in the surplus to €185 million. The OHIM/EUIPO surplus is summarised below.

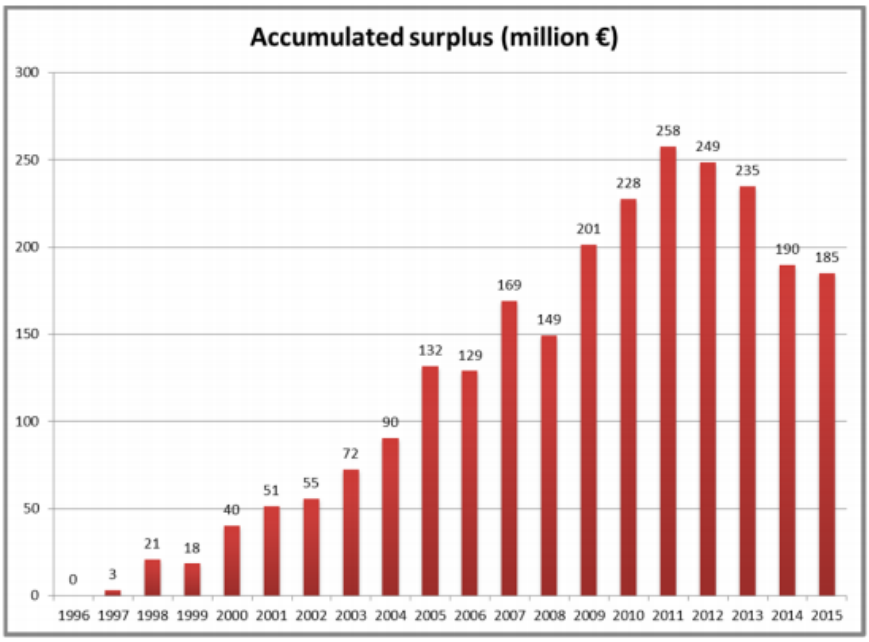
[57] European Commission/Council/Parliament (2012) Joint Statement, available at https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

[58] See https://euobserver.com/institutional/132723

[59] Deloitte (2013): The income of fully self-financed EU agencies and the EU budget, available at http://www.europarl.europa.eu/RegData/etudes/etudes/join/2013/490677/IPOL-JOIN_ET(2013)490677_EN.pdf

[60] https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/Strategic_plan_2020/strategicplan2020_en.pdf

Figure GG: OHIM/EUIPO surplus[61]



B.6 Summary

The key conclusions include:

- While the majority of EU agencies are fully funded from the EU budget, some depend (to varying degrees) on other sources of funding, including industry fees/charges or contributions from national authorities.
- Our analysis indicates that the European Aviation Safety Agency (EASA) and the European Medicines Agency (EMA) are the two agencies that are most similar to ECHA in terms of their sources of funds. EASA, EMA and ECHA all combine income from fees with contributions from the EU budget.
- The charging of fees has a number of advantages, including[62] ensuring that there is demand for the service provided and high quality of service delivery, a direct link between service use and funding, and a reduced pressure on the EU budget.
- A prerequisite for charging fees to industry is the provision of services to industry.
- The degree of transparency provided to industry stakeholders varies widely (EASA vs EMA).
- Different agencies rely on different fee models (e.g. flat fees, variable fees, annual fees, etc.), each of which has distinct advantages and disadvantages.

[61] See https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/Strategic_plan_2020/strategicplan2020_en.pdf

[62] European Parliament (2018): Specifications for an analytical study for the Committee on Budgets, "Potential revenue from the extension of charging fees by EU Agencies", available at: https://www.politico.eu/wp-content/uploads/2017/11/SPOLITICO-17111611370.pdf

B.7 Full list of EU agencies and joint undertakings

Table 15: EU agencies and joint undertakings

Acronym	Full name	Staff	2015 budget (€m)	% of EU budget	Website
ACER	Agency for the Cooperation of Energy Regulators	90	15.8	0.01%	https://www.acer.europa.eu
BEREC Office	Office of the Body of European Regulators for Electronic Communications	27	4	0.0024%	https://berec.europa.eu
BBI JU	Bio-Based Industries	22	209.4	N/A	https://bbi-europe.eu
CDT	Translation Centre for the Bodies of the European Union	200	49	0%	http://cdt.europa.eu
CEDEFOP	European Centre for the Development of Vocational Training	119	18.35	0.01%	http://www.cedefop.europa.eu
CEPOL	The European Union Agency for Law Enforcement Training	51	8.5	0.005%	https://www.cepol.europa.eu
CS 2 JU	Clean Sky 2 Joint Undertaking	42	351.9	0.22%	http://www.cleansky.eu
CPVO	Community Plant Variety Office	45	15 (18 in 2016)	0%	http://cpvo.europa.eu
EASA	European Aviation Safety Agency	833	150 (142 in 2016)	0.022%[63]	https://www.easa.europa.eu
EASO	European Asylum Support Office	126	15.9	0.01%	https://www.easo.europa.eu
EBA	European Banking Authority	151	33.5	0.02%	http://www.eba.europa.eu
ECDC	European Centre for Disease Prevention and Control	290	58.4	0.036%	https://ecdc.europa.eu/en/home
ECHA	European Chemicals Agency	600	107	0.003%	http://echa.europa.eu
ECSEL JU	Electronic Components and Systems for European Leadership				https://www.ecsel.eu
EDA	European Defence Agency	130	30.5	0%	https://eda.europa.eu
EEA	European Environment Agency	205	41.7	0.02%	https://www.eea.europa.eu
EFCA	European Fisheries Control Agency	57	9.2	0.0056%	https://www.efca.europa.eu

[63] 2016: fees and charges 96, EU subsidy 39, multiannual special projects 7

Acronym	Full name	Staff	2015 budget (€m)	% of EU budget	Website
EFSA	European Food Safety Authority	447	76.9	0.049%	http://www.efsa.europa.eu
EIGE	European Institute for Gender Equality	42	7.62	0.0049%	http://eige.europa.eu
EIOPA	European Insurance and Occupational Pensions Authority	137	20.6	0.0127%	https://eiopa.europa.eu
EIT	European Institute of Innovation & Technology	59	295.1	0.18%	https://eit.europa.eu
EMA	European Medicines Agency	890	304.1	Close to 0%	http://www.ema.europa.eu/ema/
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction	100	15.3	0.0094%	http://www.emcdda.europa.eu
EMSA	European Maritime Safety Agency	207	54.2	0.03%	http://www.emsa.europa.eu
ENISA	European Union Agency for Network and Information Security	84	10.1	0.0056%	https://www.enisa.europa.eu
ESMA	European Securities and Markets Authority	194	39.4	0.002%	https://www.esma.europa.eu
ETF	European Training Foundation	130	20.1	0.01%	http://www.etf.europa.eu
EU ISS	European Union Institute for Security Studies	24	5.35	0%	https://www.iss.europa.eu
EU-LISA	European Agency for the operational management of large-scale IT systems in the area of freedom, security and justice	140	67.6	0.04%	https://www.eulisa.europa.eu/Pages/default.aspx
EU-OSHA	European Agency for Safety and Health at Work	64	15.2	0.0093%	https://osha.europa.eu
EUIPO (formerly OHIM)	European Union Intellectual Property Office	793	384.2	0%	http://euipo.europa.eu
EUROFOUND	European Foundation for the Improvement of Living and Working Conditions	108	21	0.013%	https://www.eurofound.europa.eu
EUROJUST	The European Union's Judicial Cooperation Unit	350	33.8	0.02%	http://eurojust.europa.eu
ERA	European Union Agency for Railways	160	24.7	0.015%	http://www.era.europa.eu

Acronym	Full name	Staff	2015 budget (€m)	% of EU budget	Website
EUROPOL	European Police Office	1,008	95.4	0.059%	https://www.europol.europa.eu
F4E	European Joint Undertaking for ITER and the Development of Fusion Energy	463	385.2	0.27%	http://fusionforenergy.europa.eu
FCH 2 JU	New Energy World Joint Undertaking, Fuel cells & Hydrogen for Sustainability	26	114.6	0.07%	http://www.fch.europa.eu
FRA	European Union Agency for Fundamental Rights	107	21.6	0.013%	http://fra.europa.eu/en
FRONTEX	European Border and Coast Guard Agency	366	143.3	0.09%	https://frontex.europa.eu
GSA	European Global Navigation Satellite Systems Agency	140	27.6	0.02%	http://www.gsa.europa.eu
IMI	Innovative Medicines Initiative	47	315.2	0.19%	https://www.imi.europa.eu
SatCen	European Union Satellite Centre	120	17.9	0.0013%	https://www.satcen.europa.eu
SESAR JU	Single European Sky ATM Research Joint Undertaking	41	89.36	0.03%	https://www.sesarju.eu
Shift2Rail	The Rail Joint Undertaking	15	920	N/A	https://shift2rail.org
SRB	Single Resolution Board	164	22	0%	https://srb.europa.eu

Notes: Joint undertakings in italics.
Sources: EU Agencies (2016), https://euagencies.eu, Ekvad (2017), Mastio (2017), Deloitte (2013)