European Parliament

DIRECTORATE-GENERAL FOR INTERNAL POLICIES

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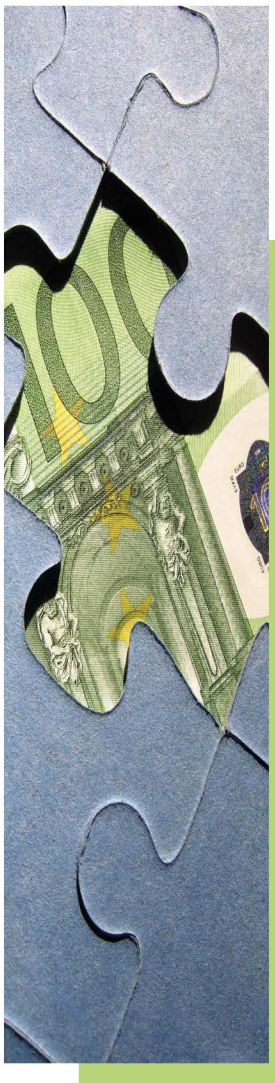

Budgets

Budgetary Control

The Cost of Non-Agencies with Relevance to the Internal Market

STUDY

EN

2016

European Parliament

DIRECTORATE GENERAL FOR INTERNAL POLICIES

POLICY DEPARTMENT D: BUDGETARY AFFAIRS

Analytical Study on the 'Cost of Non-Agencies' with Relevance to the Internal Market

FINAL REPORT

Abstract

Upon request by the European Parliament's Budgetary Affairs Committee, this study assesses the 'cost of non-agencies', i.e. the savings to MS from the existence of the EU's decentralised agencies. The study examines seven partially of fully self-financed agencies having key roles in the Internal Market. The research suggests that it is considerably less costly to carry out the tasks assigned to the agencies at the EU level than by the MS. The most significant potential impacts of a 'non-agencies' situation would be on companies seeking to trade across the EU in the Single Market. The research also confirms that added value of the agencies is widely recognised by national authorities, concerned third parties and internationally.

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This document was requested by the European Parliament's Committee on Budgets. It designated Jens Geier (MEP) to follow the study.

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LIST OF ABBREVIATIONS

BSG	Banking Stakeholder Group
BIS	Bank for International Settlements
CESR	Committee of European Securities Regulators
CRA	Credit Rating Agency
EC	European Commission
EASA	European Aviation Safety Agency
EBA	European Banking Authority
ECB	European Central Bank
ECHA	European Chemicals Agency
EIOPA	European Insurance & Occupational Pensions Authority
EMA	European Medicines Agency
EP	European Parliament
ESA	European Supervisory Agency
ESMA	European Securities and Markets Authority
EU	European Union
EUIPO	European Union Intellectual Property Office
FSB	Financial Stability Board
ICAO	International Civil Aviation Organisation
IMF	International Monetary Fund
IPO	Intellectual Property Office
JAA	Joint Aviation Authorities
NAA	National Aviation Authorities
NCA	National Competent Authority

NSA	National Supervisory Authority
OECD	Organisation for Economic Co-operation and Development
REACH	Registration, Evaluation, Authorisation & restriction of Chemicals
SME	Small and Medium Sized Enterprise
SVHC	Substances of Very High Concern
TR	Trade Repositories
WIPO	World Intellectual Property Organization

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EXECUTIVE SUMMARY

1. STUDY OBJECTIVES, AND SCOPE

The purpose of this analytical study for the European Parliament was to produce an assessment of the 'cost of non-agencies', i.e. the savings to Member States from the existence of the EU's decentralised agencies as opposed to a situation where the tasks carried out by the agencies are undertaken at the national level instead. This involved estimating the quantifiable budgetary and administrative savings resulting from the transfer of tasks from the national to the EU level. A broader assessment of EU added value was also required.

According to the terms of reference, for each selected agency, the study was to:

Analyse the impact on the EU budget and national budgets of the creation of the EU agencies and addressing their respective tasks at the European level rather than alternative solutions at the national level, and assess what synergies and economies in budgetary and administrative terms have been achieved.

As well as comparing the costs and benefits of the tasks being carried out by the EU agencies and individual Member States, the study should also allow a comparison to be made against the EU Member States as a whole.

The study should also establish whether the benefits from harmonised and increased standards across EU 28 Member States can be quantitatively or qualitatively assessed, and establish whether the value added is recognised by national authorities, concerned third parties and internationally.

More generally, this study was designed to help ensure that decisions on the resourcing of the decentralised agencies take into account the wider picture, i.e. the costs and benefits to Member States derived from undertaking tasks at the EU level. The results will inform discussions at the Interinstitutional Working Group on agencies' resources (IIWG).

The study examines seven partially or fully self-financed EU agencies that have key roles in the Internal Market. The seven agencies were: 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).

2. CONTEXT

The backdrop to this study is the decision, reflecting constraints on the EU budget generally, to curb the financial and human resources committed to the EU agencies. Communication COM(2013) 519 final stipulated that there should be a yearly 1% reduction over a period of five years for all decentralised agencies taken together (equivalent to a net reduction is a reduction of 276 posts on the 6,050 posts authorised in 2013).[1] To meet the needs for additional human resources in certain agencies, the Commission also proposed to create a 'redeployment pool' by applying an annual 1% levy on the posts of all agencies[2] that would then be allocated to

[1] Communication COM(2013) 519 final on 'Programming of human and financial resources for decentralised agencies 2014-2020', 10 July 2013.

[2] Amongst the agencies covered by this study, the EBA, ESMA and EIOPA were defined as 'start-up' agencies; the REACH and CLP element of ECHA was classified as a 'cruising agency', with Biocides as "start-up" between 2014-15 and "new tasks" from 2017-2020, and PIC as "start-up" I 2014-15 and subsequently as "new tasks"; while EASA, EMA and the EUIPO were termed 'new tasks' agencies.

'start-up phase' agencies and 'new tasks' agencies. In budgetary terms, and as a result of the changes in staffing levels, the

Communication foresees a relatively modest increase in the EU budget contribution to the agencies, from EUR 758 in 2014 to EUR 821 in 2020.

3. SCENARIOS

To help assess what would happen if the EU agencies ceased to exist, we developed a number of scenarios:

- **Scenario 0** ('the status quo') - i.e. current set-up which serves as a basis for comparison with the other scenarios and enables the additional costs (and any savings arising) from 'non-agencies' to be estimated.
- **Scenario 1** ('best case') – where tasks undertaken by the EU agencies are taken on by Member States, either using existing structures and/or developing new ones. Under this scenario the EU regulatory framework and mutual recognition (where relevant) would remain in place and it would not be necessary for alternative structures to be replicated across all 28 Member States.
- **Scenarios 2** ('worst case') – i.e. a situation where the EU regulatory framework does not remain in place or remains in place but mutual recognition is eroded. In this scenario, more Member States would have to set up their own structures in place of the European agencies and companies using their services might have to apply to have their products and services registered separately in a larger number of countries than would be the case in Scenario 1.

There is of course a link between Scenarios 1 and 2, i.e. a situation could be envisaged where in the case of Scenario 1, the transfer of EU agency responsibilities to the Member States leads to differing interpretations of the EU regulatory framework, incoherent implementation and supervisory practices and/or its only partial enforcement, thereby undermining mutual recognition, where applicable. In this situation notwithstanding the existence of a common EU regulatory framework, Scenario 2 could come about.

4. KEY FINDINGS

In relation to the three objectives of this analytical study, the overall conclusions are summarised below:

The key objective of this study was to estimate the impact on the EU budget and national budgets of the creation of the EU agencies and addressing their respective tasks at the European level rather than alternative solutions at the national level. **The research suggests that it is considerably less costly to carry out the tasks assigned to the agencies at the EU level than it would be if these tasks were undertaken by the EU28 Member States.**

In 2015, the cost of operating the seven agencies was a combined EUR 1,025 million. However, the cost to the EU's budget was much lower than this (EUR 78 million) because most of the revenue (some 93%) required to cover the cost of operating the seven agencies came from fees and charges. These were paid for by public and private sector organisations in the Member States. The extent of dependence on EU funding varies with the three financial supervision agencies (EBA, ESMA, EIOPA) being more dependent on grants and the other four agencies (EUIPO, EASA, EMA and ECHA) being less dependent. Two agencies (the EUIPO and EMA) do not rely on funding from the EU budget at all.

According to our best estimates, if the Member States took over the functions of the seven agencies, the additional costs to national authorities would be around EUR 150 million to EUR 200 million (p.a. based on 2015 data). There would be no net saving therefore from a reduction in EU funding to the agencies but rather a net increase of around EUR 72-122 million p.a. (EUR 150-200 less EUR 78 million). This additional cost would arise from the need to either expand existing national agencies or to create new entities to take on the tasks previously carried out by the EU agencies. The financial implications would not of course be the same across the EU Member States. For example, some Member States might decide, because of a lack of capacity or lower demand from companies, to rely on the services provided by agencies located in other countries.

However, the most significant potential impacts arising from a 'non-agencies' situation would be on companies seeking to trade across the EU28 Member States in the Single Market and on the stability of Europe's financial system.

If the seven EU agencies' tasks were transferred to the Member States but the EU regulatory frameworks remained in place, the effects on companies seeking to register or certify a product or service would probably be quite modest (the ending of a common EU-wide system of fees and charges could in some cases lead to increased costs). However, the most significant financial implications would arise in what we have described as a Scenario 2 situation, i.e. where a lack of EU-level enforcement and monitoring by the agencies leads to the EU regulatory framework being interpreted differently across the Member States or only being partially applied. Under these circumstances, mutual recognition would be eroded resulting in the possibility that companies would have to seek certification or registration of products and services in up to 28 different countries. In reality, national entities in a small group of Member States with the necessary capacity and expertise might take over the tasks currently undertaken by the agencies on behalf of a wider group of countries. Nevertheless, even in this situation, the costs would be considerable.

Although it is extremely difficult to estimate, our analysis suggests that the additional costs to European companies of Scenario 2 situation could be as high as EUR 1 billion depending the extent to which it would be necessary to register products and services separately in different Member States (this would depend on the extent of mutual recognition but also on how extensively companies trade across the EU). Moreover, there would also be 'hidden' costs, i.e. the internal costs to companies of having to carry out multiple certification and registration requirements, and of possibly having to adapt goods and services to different national standards. The additional Scenario 2 costs in the case of financial supervision agencies are unquantifiable but lie in helping to maintain the stability of the EU's financial sector and financial markets. There are also other costs of 'non-agencies' (efficient functioning of the Single Market, the role of the agencies in international cooperation, etc) which can only be assessed qualitatively.

Some Member States would also be adversely affected by the closure of EU agencies located in their countries. In total, some 3,500 jobs in the seven agencies could be either lost or transferred from the host countries to other locations (e.g. Brussels). In addition to the direct job losses, there could also be significant indirect employment effects. For example, each of the agencies hosts meetings and other events attracting considerable numbers of visitors to the cities where they are located throughout the year. Although not possible to quantify, the indirect jobs supported by this agency-related business in the hospitality sector (hotels, restaurants, local transport, etc) and other parts of the local economies is likely to be quite significant.

The net position at the EU level would be broadly neutral with some locations (e.g. Brussels) benefiting from the employment opportunities transferred from the locations where the

agencies are presently located. Similarly, if the EU agencies ceased to exist, some new job opportunities could be created in the entities in the same countries that would be created or expanded to replace them. However, for some of the current locations (particularly the smaller cities), the effect of the 'non-agencies' scenario would not be mitigated by these compensating factors.

Under Scenarios 1 and 2, there could be an annual overall saving of EUR 78 million (2015) to the EU budget subsidy to the seven agencies. However, because the EU subsidy helps to cover the cost of providing EU policymakers with the information needed to take decisions and to monitor the enforcement of regulations, it is likely that this activity would be transferred to the European Commission if the agencies ceased to exist with little or no net saving. But the capacity of the Commission to take on the full range of agency functions could be quite limited. With the Commission affected by the same budgetary constraints as the agencies, there would be little or no scope to recruit new staff. Instead, the most likely course of action is that there would be a transfer of some of the personnel from the agencies. The Commission would probably also have to take over some other activities, for example the representative functions at an international level for the issues currently handled by the seven agencies, and there would be some additional costs of doing this.

In addition to the direct costs to national authorities and companies there would be other effects arising from the 'cost of non-agencies'. First and foremost the seven agencies have an important role in helping to ensure the efficient functioning of the Single Market and without them this would be more difficult with consequent wider negative effects. Secondly, a centralised repository of expertise and knowledge in relation to seven key sectors of the European economy would be dispersed and more costly to retrieve if the agencies ceased to exist. Thirdly, the seven agencies have an important role in coordinating the EU's position internationally on issues relating to their areas of responsibility and this would be more difficult without them.

It should be stressed that it is difficult to quantify costs of the scenarios examined in this study precisely because there are many 'unknowns'. The 'costs of non-agencies' should therefore be treated with caution and regarded as 'best estimates' only.

In relation to the third study objective, establishing whether the value added is recognised by national authorities, concerned third parties and internationally, the research feedback – as highlighted throughout this report – strongly confirms that added value is widely recognized.

Finally, a matter of interest for possible future research on the 'Cost of non-agencies' stems from the pattern observed with regard to establishing of agencies, when the political will leading to creation of an agency is triggered by a crisis or by an incident (for example, crises led to establishing European Food Safety Authority and an incident led to setting up European Maritime Safety Agency. Arguably, the creation of the agencies prevented or mitigated further incidents and crises. Assessing the long- term savings resulting from such crisis prevention or mitigation could be a topic of a future study.

1 INTRODUCTION

1.1 RESUME OF STUDY OBJECTIVES

The purpose of this analytical study for the European Parliament was to produce an assessment of the 'cost of non-agencies', i.e. the savings to Member States from the existence of the EU's decentralised agencies as opposed to a situation where the tasks carried out by the agencies are undertaken at the national level instead. This involved estimating the quantifiable budgetary and administrative savings resulting from the transfer of tasks from the national to the EU level. A broader assessment of EU added value was also required.

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1.2 'COST OF NON-EUROPE'

In recent years, the European Parliament has undertaken a series of 'Cost of Non Europe' studies to evaluate the possibilities for gains and/or the realisation of a 'public good' through common action at EU level in specific policy areas and sectors. The concept of the 'cost of non-Europe' can be traced back to a report by Michel Albert and James Ball for the European

[3] Communication COM(2013) 519 final on 'Programming of human and financial resources for decentralised agencies 2014-2020', 10 July 2013.

[4] Amongst the agencies covered by this study, the EBA, ESMA and EIOPA were defined as 'start-up' agencies; the REACH and CLP element of ECHA was classified as a 'cruising agency', with Biocides as "start-up" between 2014-15 and "new tasks" from 2017-2020, and PIC as "start-up" I 2014-15 and subsequently as "new tasks"; while EASA, EMA and the EUIPO were termed 'new tasks' agencies.

Parliament in 1983, and was given wider coverage in the landmark study carried out for the European Commission by the economist Paolo Cecchini on the cost of non-Europe in the Single Market in 1988.

The central notion in the 'Cost of Non-Europe' is that the absence of common action at the EU level might mean that, in a specific sector, there is an efficiency loss to the overall European economy and/or that a collective public good that might otherwise exist is not being realised. The concept is closely related to that of 'European added value' in that the latter attempts to identify the economic benefit of undertaking - and the former, the collective economic cost of not undertaking - policy action at European level in a particular field. The potential economic benefits of action may be measured in terms of additional gross domestic product (GDP) generated or savings in public or other expenditure, through a more efficient allocation of resources in the economy as a whole

On 13 April 2015, the European Parliamentary Research Service published the third edition of its study 'Mapping the Cost of Non-Europe, 2014-19'. The study concludes that after a full phasing-in of proposed reforms over several years, the economic benefit could build up annually to almost EUR 1.6 trillion – or about 12% of EU-28 GDP (2014). This would represent a permanent shift in EU GDP to a higher level. The following chart, taken from the 2105 report, explains how this figure is arrived at.

Figure 1: Cost of Non-Europe

Source: 'Mapping the Cost of Non-Europe, 2014-19'(April 2015)

The analysis in the study builds on a series of more detailed pieces of work undertaken for individual European Parliamentary Committees by the European Added Value Unit over the previous two and a half years, in the form of 'European Added Value Assessments' (on legislative initiatives proposed by the Parliament) and 'Cost of Non-Europe Reports' in specific policy sectors. These sectors relate to 25 areas of policy, usually in fields where there have been own-initiative or legislative initiative reports that have been passed by the Parliament by large majorities in plenary session.

The 'Cost of Non-Europe' studies focus on examining the potential gains to be obtained from completing the Single Market. The starting point of this study on the 'Cost of Non-Agencies' is therefore different insofar as the EU's agency system is already in place and the question we have been asked to answer is what would happen if a situation that currently exists ceased to do so. Despite their different perspectives, however, both approaches seek to measure European added value.

It should be stressed that research seeking to investigate the counterfactual situation of what would happen if the European agencies ceased to exist is speculative and involves questions that very difficult to ask. Moreover, it is extremely difficult to quantify possible financial and other consequences. For these reasons the research findings set out in this report should be interpreted with caution.

1.3 STRUCTURE OF THE REPORT

- **Section 2: Background and Methodology** – after providing a profile of the seven agencies covered the research we explain the methodology for estimating the 'cost of non-agencies'.
- **Section 3: 'Cost of Non-Agencies' Scenarios'** – defined three scenarios, i.e.:
  - *Scenario O* – where the agencies continue to function as at present but with the reduction in funding and resources foreseen Communication COM(2013) 519.
  - *Scenario 1* - a situation where the tasks undertaken by the agencies are taken over by Member States but the EU regulatory framework remains in place.
  - *Scenario 2* - a situation where Member States take over the agency functions but over time the EU regulatory framework is eroded as differing interpretations/partial enforcement of standards become apparent leading to a decline in mutual recognition. Companies would therefore have to register products and services in up to 28 EU Member States to trade across the Single Market.
- **Section 4: 'Cost of Non Agencies' Estimations** – examines the financial and non-financial costs of the various scenarios.
- **Section 5: Overall Conclusions** – summarises the key study findings and the conclusions with regard to the three questions posed in the Parliament's terms of reference.

2 BACKGROUND AND METHODOLOGY

In this section we summarise the scope of the research, i.e. the EU agencies that have been examined to estimate the 'Cost of Non Agencies', and explain the methodological approach to the study.

2.1 PROFILE OF THE SEVEN EUROPEAN AGENCIES

The study examines seven EU agencies that have key roles in the Internal Market. The seven agencies include four well-established agencies adopting individual decisions that are legally binding on third parties, as well as the three financial regulatory institutions. A summary is provided below with additional details in Appendix B.

- **European Union Intellectual Property Office (EUIPO)** – administers the EU Trade Mark and Design rights. These rights complement national intellectual property (IP) rights and are linked to international IP systems. Since 2012, EUIPO has been responsible for the EU Observatory on the Infringement of Intellectual Property Rights[5] and the Orphan Works Database[6]. On average, the EUIPO examines some 120,000 trademarks and 85,000 design applications annually, but in 2015 there was a marked increase to 130,400 trademark and 97,500 design applications. The Agency also works closely with national IP offices in the Member States to encourage and develop convergence of registration practices across Europe through the European Trade Mark and Designs Network, and cooperates with the largest IP bodies in the world to combat counterfeiting and piracy.
- **European Aviation Safety Agency (EASA)** – provides technical expertise to the European Commission by assisting in the drafting of rules for aviation safety in various areas and providing technical input to the conclusion of international agreements. In addition, the Agency undertakes certain executive tasks related to aviation safety such as the certification of aeronautical products and organisations involved in their design, production and maintenance. Over two-thirds (68%) of EASA's budget comes from the aviation industry with a further 8% from third countries (2015 data). This means that just 24% of the agency's annual EUR 150 million budget is funded from the EU budget.
- **European Medicines Agency (EMA)** - is responsible for the scientific evaluation of applications for European marketing authorisation for medicinal products. Under this centralised procedure, companies submit one single marketing authorisation application to the EMA. The safety of medicines is monitored constantly by the Agency through a 'pharmaco-vigilance' network. The Agency brings together the scientific resources of over 40 national competent authorities in 30 EU and EEA-EFTA countries in a network of over 4,000 European experts.
- **European Chemicals Agency (ECHA)** – became operational in 2007 and manages the technical, scientific and administrative aspects of the implementation of new chemical legislation, in particular REACH. The Agency helps companies to comply with the

[5] The management of the EU Observatory was transferred from the Commission to the EUIPO in 2012. It is a comprehensive network providing a platform for national authorities, EU institutions, the private sector and civil society to exchange views and knowledge about new IP initiatives and best practices. It also coordinates exchanges between EU and international agencies and bodies to bring efficiency to the fight against piracy and counterfeiting. Each month, there are over 6,000 visitors to the Observatory website and more than 2,000 downloads of papers and publications.

[6] The Orphan Works Database provides information related to orphan works contained in the collections of publicly accessible libraries, educational establishments and museums, as well as archives, film or audio heritage institutions and public-service broadcasting organisations established in the Member States.

legislation, advances the safe use of chemicals, provides information on chemicals and addresses chemicals of concern. After it was established ECHA also has assumed responsibility for managing the implementation of the Biocides Regulation (2012), Common Labelling and Packaging (CLP) of hazardous chemicals and Prior Informed Consent (PIC) (2012). A high proportion of ECHA's annual budget (95%) came from fees and charges for registrations under REACH and BIOCIDE during 2015, with the remainder being a grant from the EU budget. There is also a small contribution from third countries. However, for the period from 2016-2019 the contribution is expected to be closer to 65% on average (about EUR 65 million per annum).

- **European Banking Authority (EBA)** – established in 2011 the EBA's overall objectives are to help maintain financial stability in the EU and to safeguard the integrity, efficiency and orderly functioning of the banking sector. The main task of the EBA is to contribute to the creation of the European Single Rulebook in banking which provides a set of harmonised prudential rules for financial institutions throughout the EU. The EBA also plays an important role in promoting convergence of supervisory practices and is mandated to assess risks and vulnerabilities in the EU banking sector.
- **European Securities and Markets Authority (ESMA)** – is charged with enhancing the protection of investors and promoting stable and well-functioning financial markets in the European Union (EU). As an independent authority, ESMA achieves these aims by building a single rulebook for EU financial markets and ensuring its consistent application across the EU, and contributing to the supervision of financial services firms with a pan-European reach, either through direct supervision or through the active co-ordination of national supervisory activity.
- **European Insurance & Occupational Pensions Authority (EIOPA)** - EIOPA has been contributing to a single rule book for the insurance sector. The implementation of Solvency II though brings challenges to supervision where the need for a common European supervisory culture becomes necessary. This requires joint work with all National Supervisory Authorities. With the new database, aggregating Solvency II reporting data from all Member states, EIOPA will be able to develop reliable risk analysis and early warning indicators at individual, group and system-wide level and provide the NSAs with peer group comparisons, increasing supervisory capabilities at a national level. Other core responsibilities are to support the stability of the financial system, transparency of markets and financial products as well as the protection of policyholders, pension scheme members and beneficiaries alike.

The first three are well-established agencies adopting individual decisions which are legally binding on third parties. The EBA, ESMA and EIOPA make up the European System of Financial Supervision whose aim is to help preserve financial stability in Europe. The agencies received a combined total of EUR 1,040 million EU funding in the latest year for which accounts are available (2015 in most cases). This was equivalent to 13% of the overall EUR 8,053 million funding of the agencies. The combined headcount of the seven agencies represents 53% of the overall number of EU agency staff. As such, the seven agencies are quite representative of the EU agencies generally.[7]

[7] There are a total of 37 decentralised agencies. As noted in the terms of reference, in 2015, these agencies accounted for a total of 6,554 posts, amounting to 13% of all EU staff and they received a total of EUR 853m from the EU budget (less than 0.6 % of the total EU budget).

Table 1: Key Data on selected EU agencies (2015)

EU Agencies	Date established	Location	Staff*				Budget (million EUR)	
			Officials & TA	CA	SNE	Total	Total	EU grant (%)
EUIPO	1994	Alicante	731	54	63	848	384.2	0 (0%)
EASA	2002	Köln	679	82	15	776	130.4	36.4 (28%)
EMA	1995	London	587	153	35	775	304.1	3.5 (1.1%)
ECHA	2007	Helsinki	467	103	0	570	114.8	6.9 (6%)
EBA	2011	London	120	31	14	165	33.4	13.4 (40%)
ESMA	2011	Paris	137	44	21	202	36.7	9.8 (27%)
EIOPA[8]	2011	Frankfurt	86	32	19	137	21.7	8.4 (39%)
Total/ average	**n/a**	**n/a**	**2,807**	**499**	**167**	**3,473**	**1,025.3**	**78.4 (7.6%)**

Note: *Staff: TA = Temporary Agent (EU budgeted posts); CA = Contract Agent (posts funded out of agency operations budget); SNE = seconded national experts (transferred from Member States)

2.2 METHODOLOGY FOR ASSESSING THE 'COST OF NON-AGENCIES'

Before turning to the research findings, we summarise the methodology for this study and the work plan that was adopted to carry it out. Our methodology for estimating the 'cost of non-agencies' involves five main steps:

Key Steps in Estimating the 'Cost of Non-Agencies'

- **Step 1**: What is the cost of operating the seven EU agencies?
- **Step 2:** How much would it cost for national authorities to deliver the same services?
- **Step 3**: How much would it cost for other public and private sector organisations to obtain the same services delivered by EU agencies if responsibility for these services was transferred back to the national level?
- **Step 4**: How much would it cost the European Commission if the services it obtains from EU agencies were undertaken by staff from the parent Directorate-Generals?
- **Step 5**: Savings = [Step 1] minus [Steps 2+3+4] plus non-quantifiable efficiency gains.

To help assess what would happen if the EU agencies ceased to exist, i.e. Steps 2-4 in the methodology, we developed a number of scenarios:

[8] Staff numbers for the EIOPA are those actually recruited by the end of 2015. The following numbers were authorised: 90 TAs, 34 CAs and 24 SNEs.

Cost of Non-Agency Scenarios

- **Scenario 0** ('the status quo') - i.e. current set-up which serves as a basis for comparison with the other scenarios and enables the additional costs (and any savings arising) from 'non-agencies' to be estimated.
- **Scenario 1** ('best case') – where tasks undertaken by the EU agencies are taken on by Member States, either using existing structures and/or developing new ones. Under this scenario the EU regulatory framework and mutual recognition (where relevant) would remain in place and it would not be necessary for alternative structures to be replicated across all 28 Member States.
- **Scenarios 2** ('worst case') – i.e. a situation where the EU regulatory framework does not remain in place or remains in place but mutual recognition is eroded. In this scenario, more Member States would have to set up their own structures in place of the European agencies and companies using their services might have to apply to have their products and services registered separately in a larger number of countries than would be the case in Scenario 1.

There is of course a link between Scenarios 1 and 2, i.e. a situation could be envisaged where in the case of Scenario 1, the transfer of EU agency responsibilities to the Member States leads to differing interpretations of the EU regulatory framework, and/or its only partial enforcement, thereby undermining mutual recognition. In this situation notwithstanding the existence of a common EU regulatory framework, Scenario 2 could come about.

2.2.1 Scenario 0 – Status Quo

Looking in more detail at the various scenarios, as explained in above, Scenario 0 ('status quo') is not an unchanging situation in the sense that the cost of the EU agencies would remain frozen in time. Whilst overall the number of posts and the level of EU funding of the seven agencies is likely to remain more or less constant between now and 2020, in line with the 5% cuts and 'redeployment pool', some agencies will be able to grow whilst others will not be able to do so.

2.2.2 Scenarios 1 – 'Best Case'

With the first of the two 'cost of non-agencies' scenarios, Scenario 1 ('best case'), the functions of the agencies would probably be assumed by existing national agencies or government departments although they may need to take on extra personnel to handle the additional workload.

This scenario is especially conceivable in situations where the EU agencies have only recently come into existence, i.e. with the agencies that have a function in the European System of Financial Supervision, but is less likely to be feasible with the others. The situation of different Member States is also a factor because some national authorities, although already having appropriate institutional structures in place, may not have the capacity or expertise to take on additional tasks. With the other agencies (EASA, EMA, ECHA and EUIPO), the question is also whether companies registering products with their national agencies would be able to do so at a cost that would be comparable to the charges levied by the EU agencies, and whether the time and cost involved in having registrations recognised and certified across other EU Member States would be substantially different, notwithstanding mutual recognition.

2.2.3 Scenario 2 – 'Worst Case'

Turning to the second of the 'cost of non-agencies' scenarios, Scenario 2 ('worst case'), here it is assumed that at least some of the EU Member States would have to set up new agencies in their countries to handle the tasks previously undertaken at the EU level because mutual recognition is eroded and that companies would have to register products and services in up to 28 EU Member States to trade across the Single Market.

This possibility applies especially to the agencies with a role in regulating the EU's Internal Market (EASA, EMA, ECHA, EUIPO) which were in most cases established some time ago and where Member States may no longer have the national entities and expertise that previously existed. Moreover, although the EU regulatory framework would probably remain in place, differing interpretations of it or only partial enforcement, or differing capabilities across Member State to certify products and service, could – or most probably would - lead to an erosion of mutual recognition. For the EU Member States as a group, Scenario 2 could involve a situation where there is a replication of structures and functions across 28 countries which would clearly constitute a major additional overall cost compared with the existing set-up. The most significant impact, however, would be on companies and other end-users where the costs and time involved in registering products across the EU could involve dealing with 28 separate national entities.

The applicability of these scenarios varies according to the type of agency and is also influenced by circumstances in different EU Member States. We elaborate on this in Section 4 but, in short, the scenarios outlined above apply mainly to the four agencies in our sample with a role in regulating the EU's Internal Market (EASA, EMA, ECHA and EUIPO). In the case of the other three agencies (EBA, ESMA and EIOPA) which have a function in the European System of Financial Supervision, the issue of mutual recognition is not relevant. However, the question of whether new national agencies would need to be established (or the role of existing ones expanded) if the EU agencies ceased to exist is still applicable. A further consideration is that it could be that in a 'cost of non-agency' situation, the choice is not simply between functions being transferred to the Member States or not. It is for example, conceivable that some functions could be taken over by the European Commission and/or possibly by international organisations.

The 'cost of non-agencies' includes both quantifiable and non-quantifiable aspects. In relation to the latter, there are a number of potential 'non-agency' impacts relating to the sharing of expertise, networking, negotiating position vis-à-vis international organisations, etc. These potential effects would be similar in the case of both Scenarios 1 and 2. Although not included in the original scope of this study, in relation to both scenarios there is also a question regarding the EU level information gathering and policy-related tasks undertaken by the seven agencies being transferred to the staff of the various partner Directorate-Generals (the most obvious alternative to the current arrangements).

2.3 RESEARCH UNDERTAKEN FOR THE REPORT

The research plan for this study involved a number of tasks:

Task 1 – Preparatory tasks – this included desk research to analyse information on the seven agencies and previous research, and finalisation of the study methodology. The assignment started at the end of June 2016 with Task 1 being largely completed in the first half of July.

Task 2 – Mapping of EU agency financial inputs and outputs – i.e. analysis of key features that were relevant to this study for each of the seven EU agencies including financial inputs (including costs that are covered by revenue generated from charges and fees, on the one hand, and by a grant from the European Commission and other sources on the other), and on

the output side, mapping the activities of the agencies and their key stakeholders at the national and EU level.

Task 3 – Consultations with EU agencies and key stakeholders – contacts in each of the seven agencies were obtained from the European Parliament, and checklists of questions were prepared for the agencies and national authorities. In mid-July, contact was made with each of the seven agencies. Some reacted very quickly but in other cases the process of identifying appropriate people in the agencies to provide inputs to the study took longer. Where the appropriate contacts were identified in the agencies, we conducted telephone discussions based on a list of questions that was sent to them in advance (see Appendix B). At this stage in the study we also conducted interviews with several contacts in the Parliament with a particular interest in this study. In parallel with Step 1, we began Task 2, the mapping of EU agency financial inputs and outputs.

All seven agencies provided the requested information by the end of August and all the Task 3 interviews with agency personnel were completed except in the case of one of the agencies which provided very detailed written information and where it was felt more appropriate to conduct the interviews after this information had been analysed. The quality of the information provided by the seven agencies varied but was generally good. In terms of quantity, whilst some agencies provided a few pages of information, others provided much more (28 pages in one case).

In our discussions with the seven agencies, we asked each of them to provide us with contacts at the Member State level that we could interview to help assess the 'non-agency' scenario. The contacts included Management Board members of the various agencies and some 'end-users' (e.g. Airbus in the case of the EASA). The scope and timing of the assignment meant that we had to focus on a sample of countries but every attempt was made to make this representative of EU Member States generally. Interviews were carried out with key stakeholders at the national and international levels in September and early October 2016.

Task 4 – Online survey – to make the consultation exercise as inclusive as possible, an online survey was organised to ask for opinions on the 'cost of non-agencies' from national authorities and other key stakeholders, specifically public and private sector organisations that have made use of the agencies. Five of the agencies agreed to publicize the survey. The following table provides a summary of the number of interviews and survey responses obtained broken down by agency. A full list of interviews is provided in Appendix A.

Table 2: Summary – Interviews and Survey Responses (as at 14 October 2016)

EU AGENCIES COVERED BY THE STUDY	INTERVIEWS	SURVEY RESPONSES	TOTAL
European Union Intellectual Property Office	5	0	5
European Aviation Safety Agency	10	34	44
European Medicines Agency	5	1	6
European Chemicals Agency	10	11	21
European Banking Authority	6	3	9
European Securities and Markets Authority	3	1	4
European Insurance & Occupational Pensions Authority	2	0	2
EU level and others	2	0	2
Total	**43**	**50**	**93**

Task 5 – Assessment of the 'cost of non-agencies' – an analysis was undertaken of research findings to assess the impact on the EU budget and national budgets of the creation of the decentralised agencies and addressing their respective tasks at the European level as compared to alternative solutions at national level, and assess what synergies and economies in budgetary and administrative terms have been achieved.

Task 6 – Report and presentation – an interim report was submitted towards the end of September 2016 with the draft final report being submitted on 14 October 2016

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3 'COST OF NON-AGENCIES' SCENARIOS

This section presents scenarios for the 'cost of non-agencies based on the consultations with key stakeholders in the Member States and the seven agencies themselves:

- **Section 3.1:** Baseline – current and forecast cost of the seven EU agencies;
- **Section 3.2:** Functions that could potentially be transferred to national authorities;
- **Section 3.3:** Definition of counterfactual 'non-agency' scenarios.

3.1 BASELINE – CURRENT AND FORECAST COST OF THE SEVEN EU AGENCIES

We begin by setting out the current situation with regard to the cost of operating the seven EU agencies and how this is likely to develop in coming years.

3.1.1 Current cost of operating the seven agencies

As can be seen from Table 3, the combined cost of operating the seven agencies was EUR 1,025 million in 2015. On average, 7.6% of this sum was covered by EU funding although this proportion varied considerably from one agency to another.

Table 3: Summary – Financial and human resources (2015)

EU AGENCIES	STAFF	SOURCE OF REVENUE (Million EUR, 2015)		TOTAL (Million EUR)	EU GRANT %
		EU	Other		
European Union Intellectual Property Office	848	0	384.2	384.2	0
European Aviation Safety Agency	776	36.4	94.0	130.4	28
European Medicines Agency	587	3.5	300.6	304.1	1.1
European Chemicals Agency	570	6.9	107.9	114.8	6
European Banking Authority	165	13.4	20.0	33.4	40
European Securities and Markets Authority	202	9.8	26.7	36.7	27
European Insurance & Occupational Pensions Authority	86	8.4	13.3	21.7	30
Total	3,234	78.4	946.7	1025.3	7.6%

Source: Information provided by the agencies and annual reports. Notes: EUIPO: figures from 2015 Annual Report – staff number includes statutory staff (i.e. officials, temporary agents and contract agents) and seconded national experts (SNE); EMA: excludes 153 contract agents and 35 seconded national experts; EIOPA: in addition, EIOPA counted 32 CAs and 19 SNEs.

The 'cost of non-agencies' lies, in the first instance, in a theoretical saving of EUR 1,025 million, i.e. the combined operating costs of the seven agencies (2015). The saving to the EU budget (and therefore to Member States) would, however, be far less than this, i.e. the EUR 78 million shown in the above table. This is because as the above table shows, most of the cost of operating the seven agencies is funded through the fees and charges they levy for services provided to end-users and this sum would not be saved if national agencies took over responsibility for certification procedures and other tasks currently undertaken by the EU agencies.[9]

For example, the **EMA** generates 82% of its funding from the fees and charges paid by companies that are involved in pharmacovigilance procedures (assessment of periodic safety update reports, post-authorisation safety study protocols and study results, pharmacovigilance-related referrals, etc). Some of this revenue (EUR 108 million in 2015) is

[9] The only circumstances in which this would not be the case is where the national agencies decided to charge a different fees for their services and/or the volume of requests for their services changed.

then passed on to national competent authorities for the assessments they carry out on behalf of the Agency.

Almost uniquely among EU agencies, the **EUIPO** is fully self-funding and has been so during most of its existence[10]. Likewise in 2015 **ECHA** was almost completely self-funding and only required a small amount of funding from the EU budget for dealing with Biocides and PIC. However, for the period from 2016-2019 it is expected that an average of EUR 63 million will be required from the Commission. With regard to **EASA**, almost three-quarters of its operating costs are covered by the fees and other charges paid to the agency by aircraft manufacturers and other companies from Europe's aviation sector. As with the EMA and ECHA some if this revenue is used to pay national entities to carry out the certification of products and other aviation safety tasks set out in EASA's Regulation.

However, the sources of finance are far from uniform across the agencies. In the case of **EBA**, 57% of its budget for 2015 was funded by contributions from national supervisory authorities and the remainder from observers. In contrast to the EMA, the EBA does not receive fees/charges from the private sector. Having said this, **EIOPA** has engaged in first reflections on the possible future introduction of fees/charges (several issues require further clarification including the practicalities of collecting fees, legal implications in terms of EIOPA's services, the need to maintain EIOPA's independence and the implications for governance arrangement). In **ESMA's** case, 38% of its funding comes from National Competent Authorities and another 26% from fees that it collects from supervised entities (CRAs and TRs).

3.1.2 Effect of the cuts and the cost of operating the seven EU agencies

The 'cost of non-agencies' also depends on the extent of the responsibilities and workload that might be transferred from the EU agencies to Member States. A view needs to be taken not only of the static position but how the EU agencies' function is likely to develop over time. Generally speaking, the agencies remit and related workload tends to be proportionate to their age, with the older agencies (e.g. EUIPO and EMA were established in the 1990s) having responsibilities reflecting a decade-long development of their activities.

In the case of **EUIPO,** there has been a 5% per annum average growth in demand for its services even taking into account periods of economic downturn. In 2015, in relation to trademarks specifically, the agency received just over 130,000 applications which was an 11% rise compared with the previous year, indicating a further acceleration in demand. This continued during the first half of 2016 when the EUIPO received 11.5% more direct EU Trade Mark applications than during the same period in 2015. Moreover, since June 2012, the EUIPO's responsibilities have been extended to include the European Observatory on Infringements of Intellectual Property Rights[11]. However, through serious efforts to improve efficiency since 2011, the Agency has successfully increased productivity, so that it now manages 32% more trademark applications and 29% more design applications per year compared to 2010, while overall internal unit costs have declined by some 10% in the same period[12].

[10] EUIPO Strategic Plan 2020, p.40.
https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/about_euipo/strategic_plan/strategic_plan_2020_en.pdf

[11] The management of the EU Observatory was transferred from the Commission to the EUIPO in 2012, as the Agency was thought to have more expertise and dedicated manpower to be able to administer it.

[12] Additional information provided by the EUIPO shows that it has reduced its establishment plan by 4% between 2014 and 2016 and intends to reduce it by an additional 1% in the 2017 budget, amounting to a total of 43 posts. By doing so, the EUIPO will comply with the 5% objective laid down in the Interinstitutional Agreement on budgetary discipline from December 2013. It should be noted that these reductions in the establishment plan

In the case of the other older EU agencies, the increase in their workload is not new either. An evaluation of **EMA** in 2010 demonstrated that an increase in the growth of its staff had been in line with the increase of its activities - the agency's staff increased by 150% over the period 2000-08 while the fee revenue has increased by 220%. More recently, it appears that the seven EU agencies' core areas are expanding, regardless of the age of the agency. For example, the **EBA's** tasks have been extended in three core areas of its work, regulatory policy, supervisory convergence and risk assessment, as well as consumer protection and financial innovation. As a result the agency is still expanding in terms of revenue and staffing and is expected to do so until 2018-19. (In line with the 2014-20 Multiannual Financial Framework, the EBA is considered a 'new tasks' agency so the 5% reduction target is not applied.) The EIOPA, on the other hand, in addition to devising the single rulebook, ensures its implementation, provides direct support to achieve consistent and high quality supervision to ensure a level playing field and provides the tools and infrastructure to support supervision e.g. reporting taxonomies, IM tools etc. As far as **ECHA** is concerned, the REACH/CLP element of the agency's work has met the 5% reduction target (it is defined as a 'cruising' agency). However, the Biocides and PIC elements were 'start-ups' in 2014-15 and will be 'new tasks' from 2017-20, and therefore not affected by the 5% reduction requirement.

With the **EASA,** the agency's Multiannual Staff Policy Plan 2015-17 indicates that the internal technical workload relating to product certification grew from 210,890 hours to an estimated 243,174 in 2016 (a 15% increase) with a smaller increase from 51,224 hours to an estimated 54,739 hours in 2016 in the internal technical workload for organisation approvals (+7%). (At the same time the external workload in relation to these activities remained more or less constant over the 2014-16 period). The EASA has complied with the 2013 decision and has adopted a 5% staff reduction plan for the MFF period 2014-20. EASA has also achieved a further 5% staff 'redeployment pool' cut. Despite being classified in 2015 as 'an agency with new tasks', cuts have nevertheless been made but it appears that there has been only limited effects on the agency's services as EU funding has been replaced with increased revenue from fees and charges paid by the aviation industry.

Similarly, the MFF classed **ESMA** as a 'start-up agency' until 2014, a 'new tasks agency' between then and 2018, and a 'cruising speed' in the 2019-20 period. As such, although ESMA has been subject to the 5% reduction and the 1% levy, overall its establishment plan is projected to grow.

According to the **EMA**, the agency has seen a de facto 10% cut in its budget. The EMA has achieved the 5% target set by the MFF 2014-20. The Agency has also met the 5% target 'redeployment pool' target. Unsurprisingly, the EMA considers the reduction targets as having had a negative effect, especially as the agency's workload is increasing. According to the EMA this means that it cannot guarantee that work is carried out at the same speed and scope. Thus, the current financial model is not seen as sustainable in the longer run.

The **EIOPA** did not have to commit to a separate 5% reduction target since this objective has been integrated into the MFF 2014-20 by the European Commission. Whilst the start-up phase of the Agency was expected to be completed in 2014, a series of new tasks justified staff increases. This is further explained in the European Commission's Communication

coincided with a significant increase in workload, mainly as a result of an 11% growth in applications between 2015 and 2016 which has been absorbed by the Agency through internal productivity improvements. However, since this trend has significantly exceeded the historical 5% growth during the first 20 years of the operations of the EUIPO and is expected to continue in future, the EUIPO will no longer be able to compensate business growth by means of only efficiency gains and demanding additional efforts of the staff. Accordingly, as from 2018 onwards, the Multiannual Staff Policy Plan of the EUIPO foresees increase in the establishment plan, taking account of the EUIPO's business growth as well as the annual efficiency gains of 3%.

COM(2013) 519 final, which highlights the additional tasks including the proposal for a new Insurance Mediation Directive (COM(2012)360), the development of main supervisory tasks (including joint on-site inspections), consumer protection and financial stability (i.e. reporting under the Solvency II Directive). 'Cruising speed' for EIOPA is only expected in 2019-20 and until then the agency staff contingent is expected to rise from 80 in 2013 to 112 in 2020.[13]

Table 2 below provides an overview of the expected evolution in staff for the seven agencies as foreseen by the Commission in its 2013 Communication on programming of human and financial resources for decentralised agencies 2014-2020. It suggests a rather uneven picture in terms of savings. Indeed, a considerable growth in terms of number of posts is expected for EBA (+56%), ESMA (+35%) and EIOPA (+40%) while the other four agencies are forecast to cut posts (between 4-10%).

Table 4: EU Agency posts expected evolution 2014-20

Agency	Number of posts in 2013	5% staff reduction	1% annual levy for the pool	Allocation from the pool	Total evolution 2014-2020	Number of posts in 2020	% of posts lost/ gained
EUIPO	861	-43.5	-43.5	-	-87	774	-10%
EASA	692	-34.5	-34.5	+16	-53	639	-8%
EMA	611	-30.5	-30.5	+38	-23	588	-4%
ECHA	451	-18	-29	-	-47	404	-10%
EBA	93	-4.5	-5.5	+62	+52	145	+56%
ESMA	121	-6	-6	+54	+42	163	+35%
EIOPA	80	-4	-4	+40	+32	112	+40%
TOTAL (average)	2,909	-21.14	-21.86	42	-12	2,825	+14%

Source: COM(2013) 519 final and authors additional calculations. Note: *chemicals activities only

Although data for the **EUIPO** is not available in the Communication '*Programming of human and financial resources for decentralised agencies 2014-2020*' (COM(2013) 519 final), data covering current FTE posts and plans has been provided to us by the agency. EUIPO has reduced its establishment plan by 4% in the 2016 budget and intends to reduce it by an additional 1% in the 2017 budget, thus achieving the 5% reduction target that year. The 5% reduction in the establishment plan of the EUIPO amounts to 43 posts. It should be noted that these staff reductions coincided with a significant increase in workload, mainly as a result of an 11% growth in applications between 2015 and 2016. This trend has significantly exceeded the historical 5% growth during the first 20 years of the operations of the EUIPO.

Overall, therefore, the future overall cost to the EU budget of operating the seven agencies is likely to decrease although in three cases (the EBA, ESMA, EIOPA) the number of posts is expected to increase. In relation to these three financial supervision agencies, there is the possibility of the EU subsidy being at least partially replaced by fees that would be levied on companies in the EU's financial services sector although deliberations in this regard are at a relatively early stage.

[13] European Commission (2013) Communication from the Commission to the European Parliament and the Council, Programming of human and financial resources for decentralised agencies 2014-2020, COM(2013) 519 final, 10 July 2013.

3.2 FUNCTIONS THAT WOULD POTENTIALLY BE TRANSFERRED TO MEMBER STATES

The cost of 'non-agencies' to Member States depends of course on the extent to which national authorities would need to replicate the activities of the different EU agencies. Likewise, there could be costs in a 'non-agency' scenario to users of the EU agencies' outputs and these also need to be taken into account. Just as the nature of funding varies so too does the nature of outputs produced by the different agencies and the importance of their roles in relation to different key stakeholder groups - national authorities, the private sector, international organisations and, to a lesser extent, individual citizens.

3.2.1 National authorities

All seven agencies work with national authorities and entities to promote standardisation within their respective remits. Thus, the **EMA** has developed scientific guidelines in consultation with regulatory authorities in the Member States to help applicants prepare marketing authorisation applications for human medicines. The guidelines reflect a harmonised approach of the Member States and EMA on how to interpret and apply the requirements for the demonstration of quality, safety and efficacy set out in the EU directives.

Likewise, the **EUIPO** works with national Intellectual Property Offices to harmonise the tools and practices for registering trademarks and designs. It has invested EUR 50 million in a Cooperation Fund that aims to streamline working methods and modernise IP offices through the use of up-to-date administrative solutions, such as common IT tools. The EUIPO Convergence Programme also works with the national IPOs and user organisations to reach common ground in areas where there are different practices, for example regarding the classification of goods and services. Finally, the Agency manages a register of all the trademarks and designs that have been filed with the EUIPO, containing some 1.3 million EUTMs and 700,000 RCDs.

The **EASA** is increasingly involved in international standardisation activities as a result of the implementation of new Bilateral Aviation Safety Agreements (BASAs) and the enlargement of existing arrangements. **ECHA's** activities that would have to be transferred to national authorities include the work defined in the regulations it administers (e.g. the registration, evaluation, authorisation and restriction of chemicals, updating and maintaining the chemicals database, agreeing definitions and standards with other Member States for chemical identities, interpretation of the regulations, and harmonising supervision and enforcement procedures). The Member States would also have to deal with the individual Substance Information Exchange Fora (SIEFs) in question. This involves not only operational activity at intra-Member State level but also a great number of exchanges with other Member States. Much of the extent of testing and knowledge required are new and did not exist before the regulation, and often requires highly specialised knowledge.

The **European Supervisory Authorities (ESAs)**[14] provide platforms to interact with their members and other stakeholders. This is achieved via working groups, round tables, etc, which allow for a consultation process in the production of, for example, technical standards and guidelines. Similarly, they provides a range of services to national authorities to help ensure the consistent application of the regulatory banking framework across the EU in accordance with the Single Rulebook, and facilitate the investigation of alleged incorrect or insufficient application of EU law by national authorities. The ESAs focus on consumer protection, both through prudential and conduct of business regulation. Misconduct by firms may not only harm individual consumers, but may also have a wider prudential impact posing a threat to

[14] The European Supervisory Authorities are the three EU bodies: EBA, EIOPA and ESMA.

the stability of the financial sector. Their services are of relevance to users in all Member States.[15]

More specifically, **EIOPA** and **ESMA**, primarily contribute to consistent implementation at national level of EU financial market legislation, in particular through development of a regulatory framework, namely the Single Rulebook, and by providing a forum for sharing best practices and training of supervisors. The agencies help to prevent regulatory arbitrage (or forum shopping) through supervisory convergence (i.e. ensuring that EU regulations are applied in a consistent manner across the EU/EEA) and they provide active coordination of national supervisory activity and supports joint IT systems.

3.2.2 Private sector users

The seven agencies provide various services to private sector companies across a wide range of sectors of the European economy. The relationship to relevant industries is dependent on the various agencies' remit.

Thus, the **EMA** provides services to companies in the pharma sector that want to launch new medicines in the European market. Indeed, fees for services paid by pharma companies are also the biggest income source for EMA (73% of total revenues in 2010). The **EASA** facilitates the civil aviation market in Europe, which means that any organisation which wishes to operate or use a product within the air space of the EASA's Member States must comply with the agency's certification and standardisation process. EASA's services have a global reach to private sector companies given the unique, globalised nature of civil aviation; all international traffic flying into the EU including supporting aspects (mechanics, operators, crews etc.) fall under EASA's competencies. EASA has a close relationship with European private sector companies in the aviation sector such as Airbus.

Apart from the main remit of granting pan-European intellectual property rights to private sector companies, the **EUIPO** has developed a number of enforcement tools that provide companies facing counterfeiting offences with assistance and access to information exchange about their problem. The EUIPO also provides training for private sector associations, such as rights owner associations, who subsequently convey the knowledge to their members, and they are frequently involved in national awareness campaigns on the importance of IP and the consequences of infringement. Last but not least, the EUIPO publishes a range of studies and reports on IP issues that are frequently used by private sector organisations in their work on raising awareness.

ECHA has strong links with Europe's chemical industry but as most products on the market contain or use chemicals at some stage of their manufacture or marketing, the agency has a very wide range of contacts with manufacturers, importers and downstream users of chemicals. Most of this contact is through various EU and national level industry associations. ECHA registers the substances used by the chemical industry, without which they cannot place them on the market, and also identifies substances of very high concern (SVHCs) that may need specific conditions placed on their use (authorisation or restriction). The agency also provides a forum in which member state organisations can reach agreement about technical chemical and legal interpretations that are then applied in a consistent manner throughout the EU- which means that individual enterprises do not have to go about this on an individual

[15] Interview feedback confirms the absence of readily available statistics on users per Member State. For example, whilst some of the concerned industry sectors might be physically located in specific countries, they tend to operate at a cross-border level and this constrains quantification of users per Member State. There are a few examples of specific outputs targeting only certain countries, e.g. the balance sheet reviews conducted in Bulgaria and Romania.

member state by Member State basis for the different chemical substances involved. Industry associations interviewed value this aspect of ECHA's work very highly.

Turning to the financial sector agencies, the **EBA's** main objective is to provide a single set of harmonised prudential rules for financial institutions throughout the EU. These rules are included in the Single Rulebook and which is a key reference to the private sector. However, the EBA does not have extensive direct contact with companies. Rather, the EBA operates through its Banking Stakeholder Group (BSG) which is a consultation group with stakeholders in areas relevant to the tasks of the agency. It is composed of 30 members appointed to represent in balanced proportions credit and investment institutions operating in the EU, their employees' representatives as well as consumers, users of financial services, academics and representatives of SMEs.

The EBA's sister agency **ESMA** contributes to the consistent implementation at national level of EU financial market legislation, in particular through development of a regulatory framework which contributes to creating a level playing field for investors and issuers. ESMA provides information on market developments, risks and opportunities via public registry and databases, investor warnings (where necessary); it undertakes certification/registration of firms in the EU and outside the EU; and it carries out direct supervision of credit rating agencies and trade repositories. Financial institutions participating in EU capital markets benefit from ESMA's work, including stock exchanges, other trading venues, banks, brokers, asset management companies, clearing houses, TRs, CRAs, insurance companies, pension funds, private equity companies, hedge funds, data providers, issuers of securities, auditors, accountants, etc. Institutions may be domiciled in the EU or be non-EU institutions offering services in the EU market. ESMA estimates that more than 20,000 entities may be affected by ESMA activities.

In the case of the **EIOPA**, there are currently no fees and charges from private sector organisations. However, this could change and EIOPA has engaged in first reflections on the possible future introduction of fees and charges. Several issues require clarification, e.g. the practicalities of collecting fees (e.g. via the national level or directly from companies); legal implications in terms of EIOPA's services; the need to maintain EIOPA's independence and have governance arrangements reflect the new budget structure, etc.

More generally, it is argued that the current funding system of the ESAs seems to have reached its limits: the ESAs are in constant competition with the NCAs regarding funding; and, secondly, that the complexity and limitations of the European budgetary approval process make it difficult to respond to ESA resource needs in a flexible and timely manner.[16] There is also an issued of ensuring independence. The IAIS Committee Principles foresee that a supervisor is financed in a manner that does not undermine its independence and has discretion to allocate its resources in accordance with its mandate and objectives and the risks it perceives. Likewise the IMF recommended modifying the ESAs funding arrangements to give them greater responsibility and autonomy in staff and budget management and the European Parliament has called for the reinforcement of the independence of the ESAs from the EU Commission.

[16] The Mission Letter for former Commissioner Hill already referred to the possibility of introducing fees / charges: 'Reviewing the functioning and the operation of the European Systemic Risk Board and the three Supervisory Agencies ("ESAs"), including their interaction with the Single Supervisory Mechanism and the Single Resolution Mechanism. Particular attention should be paid to reviewing the governance and the financing of these Agencies. On the latter, you should find a way to eliminate EU and national budgetary contributions to the ESAs which should be wholly financed by the sectors they supervise'.

3.2.3 EU institutions and international organisations

Thirdly, the agencies provide services to EU institutions and also have a role in relation to international organisations. With regard to the EU institutions, all the agencies provide information and advice to policymakers in the Commission and the Parliament.

The agencies also have international roles. Thus, the **EMA** has close contact with the FDA in the US and with the WHO. Likewise, **EASA** cooperates with its counterparts in USA, Canada and China and also on a multi-lateral basis through the International Civil Aviation Organisation. The **EUIPO** cooperates with EUROPOL, CEPOL and EUROJUST to strengthen national law enforcement authorities and provide them with training and knowledge building. At an international level, it works closely with the four largest intellectual property offices in the world (USPTO, JPO, KIPO and SAIC/SIPO under the 'TM5/ID5' [17]) and organises technical bilateral cooperation with 37 non-EU IP offices in an effort to strengthen IP protection systems and achieve convergence of practices. Furthermore, the EUIPO cooperates with international organisations such as the European Patent Office, the World Intellectual Property Organization and the Organisation for Economic Co-operation and Development. The agency is also involved as implementing agency in four EU-funded IP projects with China, ASEAN, India, Russia and Latin America. Moreover, in 2012 the Agency took over the management of the European Observatory from the European Commission and was entrusted with the responsibility to establish and manage the Orphan Works Database.

With **ECHA**, there is a great deal of collaboration and knowledge sharing with the OECD, as well as linkages with other chemical regulatory authorities in countries such as the USA, China and South Korea. **EIOPA** is committed to contribute to the establishment of global standards. In particular, its mission is to ensure a strong European supervisory voice within the IAIS by developing a consistent position of the 28 EU representatives. It is the task of EIOPA to promote the convergence of the approaches of the EU National Supervisory Authorities towards different regulatory and supervisory issues and bring in its work undertaken under the Solvency II regime[18] as well its interaction with its members.

In the case of the **EBA**, **ESMA**, and **EIOPA**, these agencies work together through the Joint Committee (JC) which is a forum for cooperation that was established in 2011[19]. They also have an important international role. The European Parliament requested in its report on "EUs role in the framework of international financial, monetary and regulatory institutions and bodies"

[17] The world's five leading trademark and design offices, the EUIPO, the Japan Patent Office, the Korean Intellectual Property Office, the State Administration for Industry and Commerce of China and the United States Patent and Trademark Office.

[18] With Solvency II in force and in its final phase before full implementation, the EU is significantly influencing the international debate with regard to the development of a risk-based supervisory framework and the basic sound principles of Solvency II will therefore be applied internationally. This means that the international capital standards should incorporate the fundamental principles underlying Solvency II: a total balance sheet approach, clear and transparent target criteria for calibration of capital requirements, explicit recognition of risk diversification and consideration in capital requirements of all the material risks to which the group is exposed. The objective is to foster global convergence and consistency of supervisory practices and allow Solvency II to be one of the practical implementations of the international standard. That does not mean that the global capital standards will mimic Solvency II.

[19] The Joint Committee must meet at least twice a year with the objective of strengthening cooperation between the three ESAs (EBA, EIOPA and ESMA). It is composed of the Chairpersons of the ESAs and chaired by one ESA Chairperson for a rotating 12-month term. Through the JC, the three ESAs coordinate their supervisory activities in the scope of their respective responsibilities regularly and closely and ensure consistency in their practices. In addition to being a cooperation forum, the JC plays an important role in the exchange of information with the European Systemic Risk Board (ESRB) and in developing the relationship between the ESRB and the ESAs. This role can only be played at a supranational level - having the unique possibility to coordinate across all three sectors (banking, securities and insurance and pensions), despite all the different national institutional supervisory arrangements.

to have greater involvement in global discussions on regulatory standards for systemically important insurers.

Members of the Committee on Economic and Monetary Affairs argued in a report that this is necessary to ensure global standards in the making do not clash with European rules for insurance companies. MEPs have repeatedly expressed concerns that they are losing the final word over financial regulations to the plethora of global standard setters, such as the Financial Stability Board (FSB), the International Association of Insurance Supervisors and the Basel Committee. Parliament's report makes a series of proposals to counteract that. MEPs propose the formalisation of financial dialogue between the Commission, Parliament and the Council to define negotiation remits in the run-up to major discussions. They call for mechanisms that bind Member States to common EU positions, when Member States have individual representation, and call on international organisations to allow EU representatives full participation in discussions.

The case of **EIOPA**, which does not have a seat at the FSB, has been highlighted in the report. The FSB was set up by the G20 in the aftermath of the financial crisis to address the threat of too-big-to-fail financial institutions.

3.2.4 European citizens

Last but not least, the activities of all the EU agencies ultimately benefit European citizens and remit-specific end-users although these are not their primary target groups. The relationship with wider societal users takes different forms. As mentioned above, **EIOPA** is focused directly on consumers. **ESMA's** end-users are ultimately individual citizens (savers, retail investors) in addition to institutional investors and issuers as benefitting from the stronger rules developed by ESMA. In line with its remit, the **EMA** considers patients and family doctors to the main end-users. In addition to the abovementioned stakeholders, the ECHA has a wide range of NGO stakeholders given the health safety and environmental aspects of chemicals, protection of animals against cruelty, as well as trade unions and consumers in general. **EASA** ensures the highest level of common safety for consumers flying in or out of Europe and has executive powers to ground any flight craft that contravenes safety regulations and standards.

In the case of the **EUIPO**, several of its services benefit the general public at large. For example a FAQ service that allows citizens to find answers to copyright related questions, or a website called Agorateka ('Aggregator of legal offers') providing information on legal offers of music, films and other types of digital content to citizens and consumers across Europe, not to mention their awareness raising activities and studies that are widely disseminated in the media and through national IPOs. More widely, since industry relies on intellectual property rights to support innovation and maintain competitiveness, it can be argued that the work of the EUIPO benefits the EU economy and society at large. With the **EBA**, **ESMA** and **EIOPA**, citizens benefit from efforts to promote financial stability and prudential practices in private sector entities that have responsibility for managing their money and thus improve business conduct.

Ultimately, these EU agencies' stakeholder groups could deal with national entities (assuming they existed) if the EU agencies ceased to exist. However, there could be additional costs and complications in accessing the Internal Market if authorisation of products and services need to be done at national level in 28 different EU Member States. In relation to the international stakeholders, there would clearly also be greater complexities in dealing with EU Member States individually. We examine these possibilities below.

In addition to the consequences for national authorities, there would be an effect on the end-users of EU agency services arising from 'cost of non-agencies' scenarios. The question, for the purposes of this research, is whether alternative structures to the current agency set-up would mean that users would have to pay more (or less) than they currently do for the same or similar types of services.

3.3 DEFINITION OF COUNTERFACTUAL 'NON-AGENCY' SCENARIOS

As noted earlier (Section 2), to help assess what would happen if the EU agencies ceased to exist, we have developed a number of scenarios. In this section we examine the most likely scenario for each of the seven EU agencies.

3.3.1 European Union Intellectual Property Office

Prior to the creation of the EUIPO, trademarks and designs could only be registered on a country by country basis. Under the current setup, there is a two-tier system in which companies can choose to register trademarks or designs either through the EUIPO which are then valid across all Member States, or register them with one or several national IPOs which only provides protection across the respective Member States. The activities of the EUIPO are established through a number of EU regulations, most recently amended in December 2015.[20]

In relation to Scenario 0 ('status quo'), the EUIPO is fully self-financing with all its activities funded by the registration fees received from users and not by the EU budget. The surplus that is generated is invested in additional activities as described above, including cooperation activities with national IPOs (harmonising registration practices and developing new tools), running a comprehensive IP network (the Observatory) and working with international IP bodies to combat counterfeiting and piracy. Turning to Scenarios 1 and 2, it can be assumed that companies that are only interested in IP rights registration in one (or a few) Member States would make use of the national systems. The main consequences would be for enterprises wishing to achieve recognition for their IP rights across the EU as a whole.

As regards Scenario 1, abolishing the EUIPO and transferring responsibilities to the Member States would require existing national IPOs to expand their activities considerably. Not only are the IPOs unlikely to have the capacity and expertise to cope with the additional workload that such large numbers of applications as experienced by the Agency would require, but extra costs would inevitably arise as compared with the current situation, both for the IPOs but certainly also for the companies submitting an application. Furthermore, even if the EU regulatory framework continued to be in place, the national IPOs would not be able to provide EU-wide registration services unless the current legal framework was substantially modified to allow all or some national IPOs to grant IP rights that apply across the whole EU. This could theoretically be done; however, such re-negotiations of the key features of the current system might be extremely difficult taking as an example the experience regarding patents where the attempts to establish a European 'unitary patent' with uniform protection across the EU have taken several decades[21].

[20] The most recent reform of the Agency's regulatory framework resulted in the adoption of Regulation 2015/2424. The reform of the Agency's founding Regulation was part of a broader review of the European trade mark system which also included the new Directive 2015/2436 to approximate the laws of the Members States relating to trade marks. Furthermore, responsibilities were assigned to the Office also through Regulation 6/2002 on Community designs and Regulation 386/2012 regarding the European Observatory on Infringements of Intellectual Property Rights.

[21] https://ec.europa.eu/growth/industry/intellectual-property/patents/unitary-patent_en

International agreements which have certain similarities to the situation envisaged under Scenario 1 have existed since long before the present EU Trade Mark and Design systems were introduced and it is still possible to register a trademark or a design in different Member States through the WIPO[22]. Similarly, based on the European Patent Convention, patents can be registered in 38 European countries through the EPO[23]. However, these are not global or EU-wide rights, since the WIPO and the EPO simply channel the applications to the designated national offices. Although more efficient than users having to contact individual offices themselves, this system was considered costly and not sufficiently effective, hence the creation of the EUTM and the EUIPO.

It is likely that Scenario 1 would present many cost increases as compared to the current situation. First, it would be necessary to agree a revised regulatory framework, which could very well take a number of years and its successful outcome could not be guaranteed. If the new regime were to be enforced by national courts and the European Court of Justice as under the present arrangements, it is difficult to see any advantages of this approach over the existence of an EU agency. Furthermore, operating under a new framework would still require designation or creation of a central office to process EU-wide trademark and design applications, in order to maintain a uniform interpretation of the rules and avoid the development of divergences in practice and it would be necessary to set up a joint register to coordinate the EU applications of all the national IPOs, such as the current EUIPO register. Furthermore, opposing EUTM registrations made in other Member States, or appealing decisions, would be very complicated for users with considerable language implications and legal costs. All in all, it is difficult to imagine Scenario 1 without very high time and cost implications in order to arrive at a less effective system.

What is more, the practices and services provided by different Member States would almost certainly diverge more and more over time which would inevitably lead to a situation as envisaged under Scenario 2 with trademarks of different quality depending on where they had been originated. The additional potential for litigation and legal costs would not only generate a new administrative burden but could even discourage SMEs in particular from seeking trademark and design protection in the first place (trademarks are the most common form of intellectual property registered by SMEs). In addition, the system would lose or disperse expertise that has been accumulated since the establishment of the Agency two decades ago and would generate additional costs arising with a loss of scale. Ultimately, this would be passed on in extra registration fees for users, whereas currently, EUIPO fees are comparable to the cost of having to take out trademarks in a couple of national IPOs and of course represent a very cheap alternative to having to register trademarks and designs separately in each of the Member States.

Without a centralised approach, the current cooperation activities at the European and international levels to harmonise IP practices, develop common tools and combat counterfeiting could not continue to be provided either. Nor could the many information services and the assistance currently offered to the business community and the public. Last but not least, there would be considerable political implications as a result of both scenarios. Returning to the situation existing before the EU-wide system was created would inevitably reintroduce barriers to the free movement of goods and services and would be perceived as a failure of the European integration.

[22] The World Intellectual Property Organisation based in Geneva, Switzerland.
[23] The European Patent Office based in Munich, Germany.

In the case of the EUIPO, Scenario 1 would require expansion of national capabilities, and a significantly revised legal framework allowing national IPOs to issue EU-wide protection. In the absence of such an arrangement, companies would have to revert to a situation where they apply to Member States individually for IP protection (in effect Scenario 2). This would entail significant cost increases and is unlikely to act as a stimulus to innovation and the competitiveness of EU industry. Furthermore, it is likely to undermine the Single Market and the uniform quality of trademarks/designs and would inevitably lead to a loss in confidence among users and increased potential for litigation. In addition, economic logic would argue for the value of establishing an EU-wide secretariat for the co-ordinating and planning required to support standardisation, standards and uniformity which defies the objective of changing the status quo.

The interview programme with key stakeholders at the national level in several Member States suggested that Scenario 2 was the alternative that stakeholders considered to be the most conceivable but only if it is assumed that the Member States would be able to come to a joint agreement to continue collaboration. However, none of the interviewees were able to envisage a situation where the EUIPO would cease to exist, both in the view of the national IP offices and end-users.

A major reform and modernisation of the Agency's regulatory framework was carried out in December 2015 in the form of Regulation 2015/2424[24]. The basis for the reform was an evaluation exercise by the Commission which found that the EU-wide trademark system and its fundamental principles have stood the test of time and that the users from both the EU and third countries have accepted the system and find it useful and effective. Moreover, as a 100% self-financing body, the EUIPO is not a burden on the EU budget, it does not receive an EU grant and is fully funded by the fees received from users which also generate a surplus that can be invested in organising cooperation and harmonisation activities with the national IPOs. Scenario 2 was considered possible but seen as rolling the clock back 20 years.

3.3.2 European Chemicals Agency

In the case of ECHA, it is assumed (and most likely) that the REACH Regulation, the Biocides Regulation, CLP and PIC would remain in force and that the national entities that would take over the activities of the agency would mutually recognise each other's decisions. The principle underlying REACH is that the burden for managing chemical risk is shifted to industry so a large aspect of the cost in question is born by companies and that is likely to remain to be the case in a 'non-agency' situation.

However, as interviewees from both Member State and private sector organisations pointed out, some decisions of highly strategic importance for the future of the EU's chemicals industry and downstream users of chemicals (and biocides) would have to be taken. The first is who would take over the central database of chemical substances that has been created by ECHA to implement the REACH Regulation and disseminate information about chemicals (this is the biggest chemicals database in the world). Breaking this database and information dissemination activities down to Member State levels would be fraught with technical, human and political challenges. ECHA also provides related highly complex and secured IT solutions to companies and Member States to handle data and make decisions on risk management. ECHA's wide range of co-ordination, facilitating and catalysing activities would also have to be shared out. These activities include developing scientific opinions at EU level on chemical risk

[24] The reform of the Agency's founding Regulation was part of a broader review of the European trade mark system which also included the new Directive 2015/2436 to approximate the laws of the Members States relating to trade marks,

management, taking regulatory decisions, helpdesk activities, producing technical guidance and supporting the EU's international activities on request of the Commission. Similarly, given the one substance – one registration principle underlying the REACH Regulation, it is not clear how it would be decided which Member State would be responsible for which substances.

All EU Member States had institutions to manage the safety of chemicals in existence before the promulgation of the body of chemical legislation that ECHA manages (often a joint activity between a ministry of economics/trade and industry, and health and/or environmental departments). It is these organisations that would be expected to take over the activities that are currently carried out by ECHA. However, many of the REACH (and CLP and PIC and Biocides) activities were not carried out prior to those regulations coming into effect, so the organisations in question would be expected to expand their activities and increase staffing accordingly. Industry associations have pointed out that one aspect of this disintegration of the service delivery chain is that the organisations that take over delivery may (and have in the past and still do) have quite widely diverging cultural and technical views on interpreting legislation, considering what are acceptable risk levels, and implementing and enforcing legislation that is issued.

In the absence of some harmonising or standardising organisation or secretariat, companies wishing to market their products across the EU would have to incur many additional costs to determine what specific national requirements are, modify products accordingly, and limit their transhipment to other parts of the EU where different criteria might prevail. Not only would this lead to increased costs but also it would mean the end of the single market for chemicals products in such instances. It would also make it more difficult and costly for businesses from third countries to access an EU-wide market. This would become increasingly challenging when the authorisation of substances was in question and national interests might emerge that do not always correspond with more technical objective criteria that a neutral agency could decide on in a transparent manner. Finally, as was pointed out by one pan-EU industry association respondent, at present the language of ECHA is English. If activities reverted to Member States this would create additional costs if use of the national language was required.

The question of when any transfer of tasks to national agencies takes place would also be important. If this occurred after the 2018 registration deadline, the chemicals that need to be registered to be marketed in the EU and EEA (except for new substances that enter the market subsequently) will have been registered. Registration is also a major source of revenue for the agency, so funding in the period after 2018 might be an issue. The main remaining activities would be those dealing with the evaluation of dossiers, authorisation and restriction of chemicals, and the maintenance and updating of the database. The challenge with such work and that relating to Biocides also, is that agreement would have to be reached between the Member States.

A further key aspect of such a 'non-agencies' scenario relates to the nature of the EU chemicals industry and market. There are very pronounced territorial concentrations with over 60% of all chemical sales in the EU occurring in just four Member States (adding the next four brings the share up to some 90%). While some of the leading producing countries would see the economic logic of investment in expanding existing national agencies (or establishing a replica of ECHA) to take over the required tasks, and would have sufficient industry demand to justify recruiting specialist (and costly) chemists to deal with issues relating to toxicology and ecotoxicology, this might not be the case for all Member States. Therefore it is conceivable that in some Member States some of the ECHA activities would have to be outsourced to the private sector or even contracted out to another Member Sate with the appropriate capabilities.

In the absence of the ECHA, there would be the challenge of achieving agreement between Member States on how to carry out the on-going tasks required by the regulations. Similarly, there would be additional costs for Member States in replacing the ECHA's technical and secretarial functions. The costs of doing this would probably fall most heavily on Member States with the largest chemical industries. This would also be the case for developing and maintaining the relevant databases. It is also conceivable that in due course Member States would find that it makes economic sense to establish some form of permanent secretariat to carry out these EU-wide coordinating and planning activities, and also to maintain contact with the various EU-wide stakeholders such as the Substance Information Exchange For a as well as private sector companies, Member State committees and mixed committees such as CARACAL, as well as various NGOs. If this were not the case these stakeholders would all have to deal with Member States on an individual basis which would be a costly and labour intensive exercise.

As regards Scenario 2, if the decision was made to create new national agencies to carry out ECHA's work, given the nature of the chemicals industry and market, the key question would be whether costs could be recouped from industry. In the scenario where Member States did not recognise the registrations and other activities carried out by each other (in other words, the replacement of the REACH Regulation by something else or nothing at all), this would mean a large degree of duplication of costs with firms having to apply separately to each Member State to register products. There is the added question as to whether data and tests, and other decisions related to authorisations and restrictions, for example, carried out in one Member State would be recognised in another. The situation in Scenario 2 would be very administratively burdensome with negative consequences for the competitiveness of the EU chemicals industry as a whole.

In the case of the ECHA, Scenario 1 is the most likely in a 'non-agencies' situation. There is unlikely to be much if any scope for cost savings from the ECHA ceasing to exist. This is so because of the relatively modest level of EU and Member State funding given the tasks executed by ECHA whereas there would be a need to increase capacity in Member States and to create new structures to promote EU-level co-ordination and planning. Whether these additional costs could be recouped through fees paid by the private sector is unclear and would probably vary from one Member State to another.

Should Scenario 2 emerge, companies would have to carry out additional registrations, evaluations, authorisations, etc. for substances that are being disputed, to access those markets. This increases costs for both firms and the Member State Competent Authorities in question, causes delays and fragments the single market. All MSCAs and enterprise representative organisations were clear and unambiguous that this would be a very undesirable and costly outcome.

3.3.3 European Medicines Agency

As EMA's functions have been defined in a number of EU regulations and directives[25] , if the Agency ceased to exist, Member States would still be able to use the existing EU legal basis and common framework. However, the centralised procedure would cease to function in the way it works today. Consequently, for the EMA, in a 'non-agencies' situation, Member States would probably initially revert to Scenario 1 with the EMA's functions being assumed by existing national agencies.

[25] See http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000127.jsp

However, the National Competent Authorities' workload currently varies markedly and therefore the abolition of EMA would have a differing impact on each NCA. Most if not all agencies would incur increased costs because they would require more skilled staff and scientific expertise to take on the roles currently carried out by EMA. EMA's opinion is that the Member States could manage on their own and that the benefits of having an EU agency lie in the pooling resources and expertise (e.g. the network of 4,500 experts coordinated by EMA). Mutual recognition is important, as is a centralised system.

Prior to EMA's establishment in 1995, there was no single procedure enabling the pharmaceutical industry to market medicines throughout Europe and no harmonisation of the evaluation processes. Pharmaceutical companies therefore applied independently in each Member State. Consequently, some medicines were not available in some countries, depending on the willingness of pharmaceutical companies to assess and market the medicines in 'non-profitable'[26] countries. Also, medicines were approved at different times in different Member States.[27]

It is likely that without the EMA, Scenario 2 would come about after several years with the pharma market reverting back to its pre-1995 form which means that generally there would be overall greater impact on the pharma industry in Europe but a lesser impact on NCAs. Each pharma company would probably need to prepare and submit applications for each Member State in which it wanted to sell its products. This would also entail paying the fees as set by the individual Member States rather than the centralised EMA fee. There is a danger in this situation that if individual Member States set their individual fees and charges at different rates, then pharma companies would adjust their applications accordingly, which could result in some medicines not being available for patients in 'more expensive' countries (as was the situation before the establishment of EMA). The Commission could in theory also take on some of EMA's current tasks, but would almost certainly need external support to do so.

In terms of costs to the Member States, there is already an established NCA is all countries and hence it would not be necessary to set up a new agency at the national level to replace EMA. As the cost of processing applications (fees) is incurred at the national level, any increase in the volume of work would be compensated for by an increase in fee-based income. It could be that the larger NCAs/larger Member States would find it easier to increase their capacity compared to smaller ones. According to one source, fees charged to industry at a national level are higher than the compensation that EMA pays to the NCAs for work undertaken through the committees and hence taking on work at a national level is not constitute a financial issue for the NCAs.

The network of 4,500 experts coordinated by EMA would nevertheless need to be managed by another entity (or disappear if not used by the NCAs in a national capacity), as would the eight databases managed by the Agency.

If the EMA ceased to exist, it is likely that Scenario 1 would prevail as the EMA's functions would almost certainly be assumed by the existing National Competent Authorities, with corresponding increases in costs. Increases in costs might be compensated for by an increase in fee revenue. However, the fees and the revenues would vary from one Member State to another. National Competent Authorities would have to agree to accept each other's registration decisions.

In the case of Scenario 2, which is a realistic possibility, mutual recognition would be eroded and in this situation, there could be significantly increased expenditures by

[26] PricewaterhouseCoopers (2012) The impact on the EU and national budgets of EU agencies - case studies
[27] PricewaterhouseCoopers (2012) The impact on the EU and national budgets of EU agencies - case studies

pharma firms because of the need to register their medicines in Member States individually. The increased costs would arise from multiple registration fees but also the additional resources companies would have to devote to preparing applications to the various national authorities.

3.3.4 European Aviation Safety Agency

If EASA's tasks were transferred to national authorities, aviation activities could still function under the principle of mutual recognition. Under Scenario 1, more use might be made to the former Joint Aviation Authorities (JAA) (now the Joint Aviation Authorities Training Organisation), a grouping of Member States committed to a common set of safety standards and practices. While mutual recognition (and ICAO monitoring) would ensure uniform application of the ICAO standards, there could be differences between the levels of safety in different Member States of the EU and the EEA. This could lead to a risk of regulatory arbitrage and 'forum-shopping' where companies acquire accreditation in less-regulated Member States to ensure European-wide access. This could ultimately jeopardise the safety of European citizens.

It is more likely that if EASA tasks were transferred to National Aviation Authorities (NAAs) that the former agency's functions would be carried out on an inter-governmental basis with the EU regulations remaining in in place. This scenario would involve developing a more powerful JAA with funding from national budgets. It is the only scenario in which the European citizens' safety is not likely to be compromised. Under this scenario the various NAAs would apply a uniform system. But there would be varying capabilities with some smaller (or even larger) NAAs facing challenges in applying the complex regulation. As a result, there could well be significantly higher costs. The existing pool of expertise available to the EASA would be depleted and smaller NAAs could find it difficult to recruit staff with the necessary skills, especially for their legal departments.[28] Therefore, in a scenario where EASA does not exist the additional staff could take on the new task of engaging on an intergovernmental basis.

Additionally, new working arrangements would have to be developed with the ICAO and with regard to the overall auditing process across Member States. Even with a stronger JAA, the NAAs would need to develop bilateral agreements between all the Member States to ensure a good fit with the JAA's operational model. Instead of the EASA carrying out inspections, the NAAs would have this function under the overall framework of the JAA. It has to be noted, though, that currently national authorities already carry out inspections for EASA whereas the Agency only oversees this activity. Nevertheless, it is conceivable that where particular NAAs lack the necessary capabilities, the Member States concerned could make use of another NAA but this would ultimately raise the costs of rule-making and operating an EU-wide inspection regime, especially in situations if differing interpretations of the regulation were to arise. Another problem with a purely intergovernmental approach would be in developing new legislation. The civil aviation sector has seen an increase in the use and regulation of drones, for instance, and environmental policies that promote sustainable flying policies or biofuels. Rulemaking activities under the JAA in the past were costlier, with standardisation groups requiring more staff and more time than the EASA requires presently. While new developments such as drones are regulated at the EASA level, the research included feedback suggesting that regulatory system is sometimes overly complex and burdensome for national authorities which has led to more of a workload at the national level than existed before EASA was founded.

[28] A 2015 report on NAAs staffing indicates that there was an initial increase of staff between 2003 and 2013 at national level (of 10%) in airworthiness, followed by a small decline of 4%. Source: Study on resources deployed in the area of European aviation safety before and after the creation of EASA, 2015

However, our research suggests that national rules are likely to be biased in favour of the domestic civil aviation market and lead to the regulatory framework and existing mutual recognition agreements being undermined. It is also difficult to envisage how automatic mutual recognition would work without the centralised authority of the EASA. This suggests that the 'worst-case' scenario is possible. In the case where a the JAA initiative fails, NAAs would have to become design authorities under the ICAO and would need to certify products in their country and validate outsider products. Staff and expertise would need to be recruited to undertake this function.

There are other bodies that could carry out EASA's existing functions. At present there is no Commission DG with competencies and expertise in aviation safety. In a 'non-agencies' scenario, staff could of course be transferred from the EASA to the Commission but it would probably be necessary to set up a new structure within the Commission to do this. Another option, for countries outside the regional aviation supervisory authorities' jurisdiction, the ICAO audits aviation users. Approval activities and Member State inspections could be carried out by the ICAO. Each NAA would be subject to ICAO inspections (although there might not be any net increase in the cost of inspections given that these would replace the EASA inspections). However, the ICAO is too high level to replicate the close working relationship of the EASA with NAAs. The way in which ICAO standards are achieved by EASA's regulation are different to other third countries or regions. The Basic Regulation implemented by EASA, although complex, achieves a high level of common safety in meeting ICAO requirements. If the regulation and structures ceased to be in place, this would inevitably risk lowering the levels of common safety for aviation consumers.

Some aviation companies could, as an alternative, turn to other regional aviation authorities such as the US Federal Aviation Administration (FAA). For the private sector though there would be a high cost, both operationally in certifying products but also in terms of overall market positioning. In both Scenarios 1 and 2, European aviation producers would be in a weaker position to compete in international markets. International bodies or organisations would be likely to develop favourable rules for their domestic market to the disadvantage of European companies. The JAA, historically, did not have the international recognition or the capabilities that the EASA now has to protect and strengthen European aviation manufacturers. Furthermore, a reliance on international bodies would mean third countries, rather than EU Member States, determining the level of common safety in European aviation.

Given fees and charges generate the majority of EASA's income revenue, a non-agencies scenario would not only increase the expenditure for private sector in certification activities, but hurt the existing income fiscal-model of certification activities in accordance with a private sector facing increased costs and losing contracts or clients to international competitors. Common to both Scenarios 1 and 2 are the costs of losing a pool of expertise in civil aviation and the compromising of international cooperation efforts. Another, less significant cost (in the context of the EU28) is the effect on the local economy in Cologne with the move of around 800 staff.

In the case of the EASA, the overall conclusion is that Scenario 1 followed by Scenario 2 is most likely to apply in a 'non-agencies' situation. Assuming the current regulatory framework remained (Scenario 1), EASA's tasks could be taken over by the NAAs but rule-making and certification activities would be costlier and the resources of smaller NAAs could be strained. The impact on the private-sector, in this scenario, could be high. While the cost in the internal European airspace will be similar to now, as current activities would be carried out collectively, the costs in operating outside of the European airspace would increase (in both Scenarios 1 and 2). Participation across Member States under a JAA framework would need to be mandatory to ensure that the operational requirements of European civil aviation were met.

In Scenario 2 situation, where because of the absence of EU level monitoring by EASA the EU-level regulatory framework could be weakened because of differing national enforcement practices, aviation companies might well have to apply for their products and services to be certified in several countries. This would increase costs in relation to both fees and the resources devoted to the certification process.

Feedback from the interview programme with key stakeholders at the national level in several Member States confirms this scenario for the EASA.

On the issue of staffing national authorities if EASA did not exist, it was suggested that it could take years to recruit the staff with the necessary expertise in certification and design, especially in the case of Scenario 2. The majority of respondents to the survey indicated that rather than setting up a new entity, they would need to expand an existing entity. Those we spoke to saw the EASA as a consequence of natural development in the field of aviation with one person arguing that the "certification of aircraft and companies and different national standards would lead the industry back to the sixties". The majority of those we consulted commented that in the absence of the EU regulatory framework, market share of non-EU civil aviation producers would grow at the expense of EU based companies.

3.3.5 European Banking Authority

In the case of the EBA, the need for effective and prudential pan-European regulation and supervision of the EU banking sector would remain in a 'non-agencies' situation, particularly in view of the high degree of integration between different EU Member States' financial systems. The need to develop and implement the Single Rulebook would remain, as would the need to protect consumers' interests. Consideration would also have to be given to taking on the new tasks that the EBA will be responsible for in coming years. It can also be assumed in this instance that recognition of compliance with legislation by a bank by one Member State will automatically also mean recognition by other Member States.

If the EBA were no longer in existence its tasks would most likely be transferred to the organisations that are tasked with similar supervisory functions at a national level. In most instances, these are the central banks, although in some countries there are financial agencies or authorities that would take over such tasks. The costs of taking on these tasks which are at present born by the EU (approximately 40% of EBA funding is provided through the EU budget) would have to be taken on by the Member States, while the Member States would be able to use their direct contributions to EBA funding to pay for the activities in their national organisations taking over EBA. One further possibility is that different Member States would focus on the development of different parts of the Single Rulebook. But this could lead to fragmentation and reduced efficiency and effectiveness, as well as other possible complications, both technical and political.

Larger Member States that have greater financial responsibilities would have a particular interest in maintaining financial stability and would have more resources to invest in a national entity to carry out EBA-related activities. However, a great deal of co-ordination and planning would still be required to ensure agreement and standardisation at EU level. Some sort of external supervisory mechanism that could provide independent monitoring of developments across Member States would also be needed (possibly the ECB? But they would also have to be remunerated for this activity). As regards international commitments, an EU-level forum or secretariat would be needed to deal with relationships with organisations such as the Bank for International Settlements (implementing Basel III) and the IMF. An alternative option is that this might be done by the Commission or possibly the European Central Bank. Overall, it is clear that scale efficiencies would be lost and that the cost of transferring EBA functions to Member State entities would not produce significant cost savings.

In conclusion, in the case of the EBA it is likely that Scenario 1 would be applicable. The additional costs of carrying out the EBA's activities would have to be borne by the national authorities. Smaller Member States might have higher costs compared to others as they have smaller banking sectors and might find it disproportionately costly to find and pay for the required expertise. In reality, as is the case already in some instances, they would become or remain passive regulation adopters as they have neither the capabilities nor the need to exercise substantial influence on interpretation of legislation.

It is difficult to see any cost savings resulting from a situation in which the EBA ceased to exist, especially as in addition to the national level activities, it would be necessary to put in place EU-wide co-ordination, planning and supervision through a very fragmented system of national entities. Indeed, some countries might develop and apply alternative standards, or apply standards only in a very loose fashion which would increase systemic risk throughout the EU banking system. This might result in a Scenario 2 situation with several regulatory regimes present in the EU, reducing the potential for the single market in financial services, and raising costs to banks that need to operate dual or multiple regulatory regimes and also to national authorities who have to deal with such scenarios.

Feedback from the interview programme with key stakeholders at the national level in several Member States confirms Scenario 1 for the EBA. For example, some stated that in order translate Basel III into the EU's Capital Requirements Regulation (CRR) and the Capital Requirements Directive (CRDiV), there are so many technical standards involved that need to be interpreted and agreed between Member States' financial authorities so that they could be transferred to Level 2 and Level 3 legislation, that if the EBA ceased to exist, almost immediately another form of permanent structure of cooperation would be required.

3.3.6 European Securities and Markets Authority

The requirement to protect investors and promote stable and well-functioning financial markets in the EU would in all likelihood remain a priority in a 'non-agencies' scenario, as would contributing to the Single Rulebook for EU financial markets (with EBA and EIOPA), ensuring its consistent interpretation and application across the EU, and contributing to the supervision of financial services firms with an EU-wide reach, either through direct supervision or through the active co-ordination and convergence of national supervisory activity and practices. There is also the need to supervise specific entities such as credit rating agencies (CRAs) and trade repositories (TRs).

Under Scenario 1, all Member States would continue to be bound by EU-wide Regulation, reducing the scope for diverging national implementation procedures. The financial system regulatory, monitoring and supervisory activities would revert to the national authorities that dealt with this before the establishment of the ESMA and related regulations came into force.

The cost of Scenario 1 would be determined by the response of each individual Member State to a closedown of ESMA. This would, in turn, depend on national priorities, the size of domestic financial markets and the types of entities operating within them. It is most likely that Member States would increase capacity internally within existing institutions rather than creating new entities to deal with the increase in work to be carried out. In smaller countries it may not be viable to replicate the full range of skills and capabilities that ESMA has and other solutions might have to be sought. Training costs would also increase as each national authority would have to carry out its own capacity-building (currently ESMA runs programmes for the all national authorities). Data collection would be decentralised again, driving up cost, unless it is

decided to keep a centralised data base (however, this would also incur costs). Governance and translation costs would increase. EU funding sources would also have to be replaced and it is not certain whether fees would continue to be generated at a sufficient level, although it is probable that funding by NCAs would continue.

The table below provides an overview of the human (expressed in full-time equivalents) and financial resources (in million EUR) devoted to ESMA's core activities. While we do not have exact data on the financial resources spent on different activities other than direct supervision, we estimated the costs based on the breakdown of FTA which we have received from ESMA.

Table 5: ESMA activities and costs (million EUR, 2016)

Activities[29]	Human resources	% of total human resources	Financial resources in million EUR	% of total financial resources
Promoting supervisory convergence	100	48	17.27 (est.)	47
Assessing risks to investors, markets and financial stability	28	13	4.41 (est.)	12
Completing a single rulebook for EU financial markets	31	15	5.14 (est.)	14
Direct supervision of specific financial entities	49	24	9.75 (est.)	27
TOTAL	**208**	**100**	**36.74**	**100**

The change in costs for market users under Scenario 1 would depend on decisions taken by each Member State. Outputs and services provided by national competent authorities would not necessarily be the same as those currently provided by ESMA. For instance, if supervisory coordination was restricted to the national level, this would reinforce market deficiencies resulting from limited supervisory information exchange, which in turn would undermine investor protection and financial stability. In general, such a solution would provide for a system that is not in line with the objective of a stable and single market for financial services. Compliance cost would go up and legal certainty go down (e.g. when it comes to liability in different markets) because this scenario would lead to an inconsistent application of relevant EU law. While some markets users may welcome a reduction in EU regulation, which is considered burdensome, they would be very concerned about a breakdown of the single market in capital in the EU, which would severely undermine the basis for most of their business activities – and this outcome is not inconceivable were the EU regulatory framework adopted following the financial crisis given up. Generally, there is an expectation amongst market users that they should be treated equally across the EU28.

Another wider cost of this scenario is that the Commission would probably have to assume responsibility for representing the EU in the international arena.

Turning to Scenario 2, even with continuing existence of EU legislation, looser cooperation between national competent authorities on the basis of mutual recognition could lead to inconsistent application of rules for financial market participants, contributing to regulatory and supervisory arbitrage, disintegrated financial markets and lack of supervisory information on cross-border activities within the EU. Moreover, the NCAs could find it very difficult to agree on new rules in response to new financial crises in the future. All of these factors were elements identified as leading to the financial crisis in 2007-08 and, to the extent that they still apply

[29] These figures are based on ESMA's projections and are in line with the MFF. Both administrative and support staff are included in the table. Please note these figures include the allocation of Temporary Agents + Contract Agents + Seconded National Experts whereas the MFF provides indications only on Temporary Agents.

today, remain major impediments for regaining trust of investors to provide lending to the real economy through financial markets.

In the case of Scenario 2, a Member States would probably have to allocate significantly more resources to existing agencies since the lack of mutual recognition between Member States would essentially mean that they would have to apply for such recognition of each other on a one-to-one, bilateral basis, and companies such as the CRAs in each Member State would also have to apply separately for recognition. This would involve much more substantial costs than at present. In addition, the challenges highlighted by the De Laroisière report would, as in the case of the other financial agencies, remain.

In conclusion, given the need to continue to comply with EU-wide legislation it is probable that Scenario 1 would be applicable. The costs of making up the EU contribution would have to be taken on by Member States, probably in proportion to the size and importance of their financial systems. There might be scope for additional fee-generating activities from the private sector. However, additional costs would be incurred in developing alternative structures to promote EU-wide cooperation and planning. In the case of Scenario 2, Member States would probably have to allocate significantly more resources to existing agencies since the lack of mutual recognition would essentially mean that they would have to apply for such recognition of each other on a one-to-one, bilateral basis.

Feedback from the interview programme with key stakeholders at the national level in several Member States confirms these scenarios for the ESMA. For example, it was pointed out that EU Regulations adopted after the financial crisis in 2007-08 would most likely not be revoked along with the agency, meaning that all Member States would continue to be bound by EU-wide Regulation, reducing the scope for diverging national certification procedures. As one national competent authority indicated: "The current legal model of recent EU financial services regulation is therefore predicated on the existence of the ESAs [incl. ESMA]." In practice, NCAs would most likely increase capacity internally rather than creating a new national entity to deal with the increase in work to be carried out.

Another NCA also cautioned that while some market users may welcome a reduction in EU regulation, which is considered burdensome, they would be very concerned about a breakdown of the Single Market in capital which would severely undermine the basis for most of their business activities – and this outcome is not inconceivable were the EU regulatory framework adopted following the financial crisis did not continue to exist.

Under Scenario 1, according to NCAs interviewed, tasks currently carried out by ESMA could repatriated to the previously existing Committee of European Securities Regulators (CESR) which was a network of EU authorities promoting consistent supervision across the EU and providing advice to the European Commission. However, a NCA believes this would be difficult in practice, given that the CESR was set up before the financial crisis, and had to deal with a lot less regulation than is now in place. Moreover, CESR was not equipped with the legal means (Breach of Union law, Comply or Explain for Guidelines, and others) which now allow ESMA to ensure consistent outcomes across the EU. Indeed, the difficulty of maintaining EU rules in place in absence of ESMA is compounded by the fact that a lot of this regulation was only passed since the financial crisis, and was designed keeping in mind the existence of a supranational entity supervising such regulation.

In any case, cooperation among EU regulatory would have to continue and same or similar services as currently delivered by ESMA would have to be delivered by NCAs on a case by case basis. In such as situation, many smaller Member States would rely on advice from larger ones, driving up the cost for NCAs in the latter ones. Alternatively, legislation at EU level could itself

become more detailed and prescriptive, reducing the need for further rule-making by ESMA, but this is an outcome not deemed desirable by an NCA interviewed for this study.

3.3.7 European Insurance and Occupational Pensions Authority

The progress made towards a more integrated European supervisory system in order to ensure a level playing field and to prevent regulatory arbitrage for all actors in the insurance and occupational pensions field is likely to be jeopardized in a situation where the EIOPA ceased to exist.[30]

A 'non-agencies' situation would almost certainly result in less efforts undertaken by Member States to strengthen the supervisory framework to reduce the risk and severity of future financial crises. Should Scenario 1 come about, the need for action in the area relating to insurance and occupational pensions will remain, but in the absence of an independent coordination body there will be a lack of incentives for NSAs to comply with the European benchmark without being 'home' biased. It is not clear to what extent such initiatives were present in all EU Member States before the financial crisis, but it is conceivable that the activities of EIOPA would, in as far as possible, be continued in some way at the national level by expanding existing institutions' activities.

This would mean that to maintain a similar level of activity[31], the budgetary contributions from Member States would be retained and used for national initiatives in the area but the EU contribution (some 40% of EIOPA's current budget) would have to be obtained from other sources. There could be opportunities of generating fees or income from other sources (e.g. companies operating in the sector) and this is, in fact, currently under discussion as noted earlier. So while there could be an initial increase in costs, assuming the current EIOPA activities are continued through national entities, the cost to national authorities could be reduced if other funding sources are utilised (equally, if the Agency itself identifies other funding sources, the cost of the status quo would also decrease). Either way, it is likely that fragmentation would reduce the economies of scale currently demonstrated by the EIOPA.

As in the case of other agencies, there would be a continued need for EU-wide planning and co-ordination. This might well be more costly as efficiencies and effectiveness related to scale are lost.

If Scenario 2 were to occur, with the establishment of new agencies in at least some Member States, there would of course be additional costs. However, the main cost driver would be if the supervisory systems did not exist and as a result there was consequently a need for a country by-country ratification and approval procedure. In addition, it is unlikely that the scale of regulatory activity in many smaller Member States[32] would justify the levels of expertise

[30] The European Commission conducted an Impact Assessment in the context of preparing the EIOPA Regulation. The Impact Assessment considers different options in relation to the wider system (European Systemic Risk Council / European System of Financial Supervisors) but does not specifically discuss alternatives to the establishment of EIOPA. The different options / alternatives considered appear to relate mainly to the range and extent of competences and powers of the new system; the actual introduction of the system per se is not questioned. Recital 1 from EIOPA's founding regulation states that: 'The financial crisis in 2007 and 2008 exposed important shortcomings in financial supervision, both in particular cases and in relation to the financial system as a whole. Nationally based supervisory models have lagged behind financial globalisation and the integrated and interconnected reality of European financial markets, in which many financial institutions operate across borders. The crisis exposed shortcomings in the areas of cooperation, coordination, consistent application of Union law and trust between national supervisors.'

[31] Although the role of EIOPA as an independent body, coordinating the decision making process with all the Member States, cannot be replicated at a national level.

[32] See footnote above - as an independent body the EIOPA enhances supervisory convergence, something that would not be possible on a national level.

and specialised capabilities on a purely national basis that are currently accessible from the EIOPA.

In the event of EIOPA ceasing to exist, it is expected that Scenario 1 would occur with most of its activities being taken over by existing Member State entities. If the existing activity levels were to be maintained it would require additional funding by Member States to compensate for the lost EU contribution, although fee raising activities might be possible in the future. Under Scenario 2, the non-existence of EIOPA and the Solvency II regime, would lead to different or non-existing regimes across the Member States which would result in a fragmented internal market.

The text box below provides examples of the feedback we obtained from the survey from national authorities and companies on the various 'cost of non-agencies' scenarios.

In relation to Scenario 1, just over 90% of the survey respondents indicated that rather than setting up new agencies, an existing national entity would be expanded in the European agencies ceased to exist. Over half (55%) said it would be would be 'very difficult' to recruit the personnel required to do this with a further 22% saying it would be 'quite difficult'.

With regard to Scenario 2, 50% of the survey respondents argued that even if the EU legislation stayed in place, there would nevertheless be a danger that the varying capabilities of different national agencies with regard to enforcing common standards leading to an erosion of mutual recognition. A further 27% said this was 'quite likely'.

Examples of survey feedback on consequences of 'non-agencies'

- "Canada has signed a bilateral airworthiness/maintenance agreement with EU/EASA. If EASA were dissolved, Canada would then need to negotiate separate agreements with all EU member states. This is impractical and wasteful. In addition, each state (particularly those with aviation manufacturing and maintenance companies) would need to create its own civil aviation agency; this would take considerable time and be very expensive."
- "The establishment of the EASA and EUROCONTROL was the consequence of natural development in the field of aviation. The nature of aviation is international. The certification of aircraft and companies to different national standards would lead the industry back to the 1960s."
- "The degree of sharing good practices and access to centralized expertise may be reduced without the EBA. Also, the supervision practices may be less consistent between the countries without a centralized coordination. Finally, the continuous meetings between the Member States facilitates the development of common tools through personal interaction and shared understanding."
- "There would probably be different frameworks in the member states to ensure human health and protection of the environment. Some sort of mutual recognition of authorized/permitted/registered substances would probably be established. Costs for such decentralized authorisation systems would probably differ a lot between member states for market participants."
- "Extremely expensive and with no value added - a disaster for both European companies and foreign companies wishing to export to Europe."

- "There would be necessity to certify some products in every country. Also some European companies extending their activities in more than one country could be forced to cease their operation or to be re-certified in all countries. The cost could be extremely for large companies and could prevent operation of the small ones."
- "To skip the ECHA would generate a very serious situation. A harmonisation of chemical legislation needs a central steering agency. The collaboration between companies in different Member States would become very difficult … without ECHA we would have the need to register in each country."

4 'COST OF NON-AGENCIES' ESTIMATIONS

In this section we provide a best estimate of the 'cost of non-agencies'. It should be stressed that cost estimates are hypothetical and many of the potential costs cannot be quantified. The analysis is structured as follows:

- **Section 4.1**: Financial cost of 'non-agencies';
- Sec**tion 4.2:** Cost of 'non-agencies' to key stakeholders;
- **Section 4.3:** Other costs of 'non-agencies'.

As noted earlier, in this report the 'cost of non-agencies' is based on examining two scenarios – the first being where Member States take on the functions previously carried out by the European agencies but with the EU regulatory framework remaining in place, while the second scenario assumes that the regulatory framework and mutual recognition would cease to exist.

In relation to four of the seven agencies (EUIPO, EASA, EMA and ECHA), these scenarios have financial and other consequences for national authorities, companies that make use of agency services and the European Commission. With the financial supervision agencies (EBA, EMSA and EIOPA) the direct effects are largely confined to the national authorities although there are also wider consequences for the financial services sector as a whole.

4.1 FINANCIAL COSTS OF 'NON-AGENCIES'

The question we tackle here is whether the EUR 1,025 million cost of operating the seven agencies, or EUR 78 million cost to the EU budget (2015), would be saved or not if alternative solutions were adopted at the national level. Below we examine the costs arising from Scenarios 1 and 2 from the perspective of the seven EU agencies.

4.1.1 EUIPO

If Scenarios 1 or 2 were to come about, the most likely outcome would be that five national IP offices (in DE, ES, FR, IT, UK) would issue the bulk (e.g. around 70%) of the nearly 90,000 trademarks and 62,000 designs registered by EU users (2015) with the EUIPO[33] corresponding to 63,000 trademarks and 43,400 designs (70% of above numbers). This would be additional to the purely national trademarks/designs issued by the IPOs in these countries. We have assumed that the IPOs in these countries would require additional funding that is equivalent to the resources used by the EUIPO to handle the same number of trademarks/designs, i.e. each of the five offices would need additional funding of an average of EUR 16.3 million (63,000 x EUR 1,050 (price of EU trademark[34]) + 43,400 x EUR 350 (price of design) / 5) to cover the cost of dealing with the additional trademark/design applications. In order to deal with the remaining 30% of the EU registrations (27,000 trademarks and 18,600 designs), the other 21 national IPOs[35] would have to increase their funding by an average of around EUR 1.7 million each (27,000 x EUR 1,050 + 18,600 x EUR 350 / 21) to take on the additional business.

[33] Of the 130,000 EU Trade Marks registered in 2015, 69% emanated from EU Member States and 31% from non-EU countries. The leading EU countries were Germany (21.85%), UK (12.96%), Italy (13.26%), Spain (10.60%), France (8.31%). EUIPO website: https://euipo.europa.eu/tunnel-web/secure/webdav/guest/document_library/contentPdfs/about_euipo/the_office/SSC009-Statistics_of_EU_Trade_Marks-2016_en.pdf.

[34] Price of EU trademark filed electronically and covering 3 classes of goods/services.

[35] There are only 26 IPOs in the EU since one office, the Benelux IPO, covers 3 countries: Belgium, the Netherlands and Luxembourg.

We have assumed that the extra resources needed by the five largest offices would, in the long run, be covered by the income from registrations, but a considerable investment would be needed up front. In addition, there could be significant operational costs involved in setting up an EU-wide secretariat including a joint database of all EU registrations, which would be necessary to make the system work. The substantial modification of the legal framework would also end up being costly to Member States given the time it is likely to take. Due to the number of unknown factors, an attempt at quantifying these costs has not been made, but they are likely to be significant.

The other services that the EUIPO provides, i.e. collaboration with EU and international IP bodies to harmonise registration practices and strengthen IP protection, management of the EU Observatory and knowledge building activities (drafting studies and reports and providing training), would most probably be discontinued if the Agency ceased to exist. The loss of these services to the IP community worldwide should also be considered in the calculation although it is impossible to quantify the associated costs if these services were to be rendered by other players. What can be set out, however, is how much of the EUIPO's budget is currently spent on these other services.[36]

In relation to end-users, in the case of the EUIPO, the cost of registering a trademark in a national IPO is generally in the range EUR 150 to EUR 300 (we have assumed an average of EUR 250 per trademark and EUR 70 for a design). This compares with EUR 1,050 for a European trade mark and EUR 350 for a design issued through the EUIPO. If the EUIPO ceased to exist, and companies had to register their products separately in each EU Member State, the cost of this procedure could amount to around EUR 6,500 per trademark (i.e. EUR 250 x 26 IPOs[37]) and EUR 1,820 per design (EUR 70 x 26). At an aggregate level, this would mean that if the 90,000 EU trademark and 62,000 design applications handled by the EUIPO in 2015 were to be dealt with separately by the 26 national IPOs, the cost would be EUR 697.8 million[38] instead of EUR 116.2 million[39], or six times as much. This represents a maximum figure because in reality companies might decide to only take out trademarks or designs in certain countries. However, the estimate is directly comparable to the equivalent EUIPO cost. If companies decided to only register their trademarks/designs in half the Member States the aggregate cost would be around an additional EUR 348.9 million p.a.[40]

4.1.2 EASA

If Scenario 1 were to come about, the most likely outcome would be that the three largest National Aviation Authorities (NAAs - DE, FR and the UK) that already carry out the majority of EASA's outsourced work would take on the EASA's activities, possibly with assistance from some other NAAs (e.g. IT and NL) and possibly within a JAA framework. Based on 2015 data for EASA, these activities would include issuing approximately 3,300 certificates, 3,000 organisational approvals, and supporting validation of certificates and approvals in third countries. Under this scenario, the 451 EASA staff currently carrying out certification activities along with the 325 staff carrying out other services would transfer to the NAAs. Based on 2013

[36] Based on a breakdown of staff costs in each of their three main areas of activity, provided to us by the EUIPO, the annual costs related to managing the IP cooperation services and the Observatory (which includes knowledge building) amount to EUR 71.1 million and EUR 31.1 million, respectively.
[37] See footnote above.
[38] (90,000 trademarks x EUR 6,500 + 62,000 designs x EUR 1,820 = EUR 697.8 million)
[39] (90,000 trademarks x EUR 1.050 + 62,000 designs x 350 = EUR 116.2 million)
[40] These calculations do not take into account that end-users would face considerable additional operational, translation and legal costs having to deal with the differing procedures and languages in the Member States (which might exceed the costs of the additional IP office fees) and increased risk of litigation, nor does it take account of the additional costs linked to a situation where barriers to free movement of goods and services would be reintroduced.

data, a total of 5,100 personnel were employed by the EU's 31 NAAs, implying a substantial increase in NAA personnel.[41] Under Scenario 1, the total staff would increase to 5,876 (5,100+776 staff currently at EASA) to cope with the increased workload. Thus, whilst the costs to the EU budget would reduce, there would be a corresponding increase in costs for Member States. However, this would be largely self-financing, as at present, from fee income. Because of the difficulty in estimating a precise figure, we have assumed a net increase of 10% in costs to Member States.

In relation to end-users, the cost of certifying products via the EASA varies quite widely depending on the type of product. For each product, the EASA then offers a flat fee in accordance with Commission Regulation (EU) No 319/2014.[42] The charges would remain the same if the regulatory framework was retained, as under Scenario 1. However, if Scenario 2 came about, in the worst case where producers would have to certify their products in several Member States the costs of doing so would multiply accordingly. In all likelihood, Member States would agree on bilateral working arrangements with other countries so that smaller NAAs could rely on larger NAAs to certify products. If companies had to certify their products with the three largest NAAs (e.g. because other countries did not accept the certification of one particular NAA), then the costs could increase quite sharply for companies. For example, certifying a turbine engine with a power output of over 2,000 kW would cost EUR 1,185 million compared with the EASA fee of EUR 395,000. Likewise, certifying a fixed wing aircraft of between 50,000kg and 150,000kg which costs EUR 1.530 million through EASA would cost EUR 459 million.

In a Scenario 2 situation the fee rates set out in Regulation (EU) No 319/2014 would almost begin to vary according which NAA was carrying out the certification for a particular product. From the interviews and survey feedback, and based on the logic of dealing with complex EASA safety regulation and the additional costs of validating European certificates internationally, we have assumed a 10% increase in costs. While feedback from survey responders and interviewees suggests that larger NAAs would be able to deliver some services at a lower cost, this is likely to be only true for existing competencies (for example certifying airline operators). As many of the certification tasks have been transferred from NAAs to EASA, including engines which make up the bulk of certification activities, NAAs would see an increase in costs in re-establishing these competencies. The feedback indicating the possibility of lower costs for end users also assumes state subsidies which would vary and be constrained by national budgets. It is therefore more likely that the majority of NAAs would see a service charge either remaining the same or experiencing a slight increase (this excludes the additional costs of duplication and validation required).

EASA generates approximately EUR 91 million from certification and other services (2015) so this would mean a total cost of at least EUR 300 million to the aviation industry if it was necessary to certify products via three NAAs (i.e. 91 x 3 +10%). The EASA Regulation contains certification fees for almost 200 aviation products and it is not possible within the scope of this study to analyse the possible effects of multiple certification requirements on all products but some might need to be registered with NAAs in more than three countries.

Under Scenario 2 the cost of validating European certificates internationally might well also increase because bilateral agreements might not be maintained with third countries not recognising the certification of an individual EU Member State NAA (even under a JAA

[41] "Study on the resources deployed in the area of European aviation safety before and after the creation of EASA", Ecorys, (2013 Data), 2015 for European Commission, DG Mobility and Transport, p. 63
[42] Commission Regulation (EU) No 319/2014, http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0319&from=EN

framework). Those we spoke suggested the cost of getting this recognition for certificates would increase.

4.1.3 EMA

In relation to Scenario 1, there is already an established NCA (or several depending on the national set-up) in all EU Member States and therefore it would not be necessary to set up a new agency at national level to replace the EMA. As the cost of processing applications is incurred at the national level, any increase in the volume of work would be compensated for by a larger fee-based income as long as the agencies had the capacity to handle the increased volume of work. It could be that the larger capacity NCAs/larger Member States would find it easier to increase their capacity compared to smaller ones. However, most if not all agencies would incur increased costs because they would require more skilled staff and scientific expertise to take on the roles currently carried out by EMA (for example, the UK NCA carries out approximately 15-20% of EMA applications). Thus, whilst current fee levels would remain the same for a while, adjustments would need to be made to cover additional costs (estimated at +10%) unless Member States subsidized these additional costs.

In a Scenario 2 situation, the NCAs would take over the registration of human and veterinary medicines from the EMA. According to our research, fees charged to industry at national levels are higher than the compensation that EMA pays to the NCAs for work undertaken through the committees. In 2015, a total of EUR 108 million was committed by the EMA for payments to the NCAs (compared to EUR 96 million in 2014) with total fees and charges related to marketing authorisations amounting to EUR 255 million.[43] We have taken this latter figure and assumed that the NCAs would take over the tasks that these fees relate to.

Pharmaceuticals companies in DE, ES, FR, IT, PL and the UK would bear the brunt of these increased fees because this is where the industry is concentrated but Belgium, the Netherlands, Poland and Sweden are also rather large players. As with the other agencies, there would also be very significant (but unquantifiable) additional costs to companies in terms of staff time and other resources in having to prepare separate applications for registration of human and veterinary medicines in different Member States as in a Scenario 2 situation the procedures and criteria would vary from country to country.

There is a danger in a Scenario 2 situation that if individual Member States continue to set their individual fees and charges at different rates, then pharma companies would eventually adjust their applications accordingly, which could result in some medicines not being available for patients in 'more expensive' countries (as was the situation before the establishment of EMA).

As an illustration of the potential size of costs involved, the table below provides an overview of the national fees charges for market authorisation of a new medicinal product for human health in 10 different EU countries (AT, DK, ES, IE, MT, NL, PL, PT, SE, and SI). It should be highlighted that – although there are some similarities between the fee structures – pricing is a national prerogative, thus there are marked differences in the pricing structure, which also make the fees (and the content of services including in each fee) difficult to compare.

[43] EMA 2015 Annual Report, page 84.

Table 6: NCA fees examples

Member State/NCA acronym	Member State/NCA acronym
The Netherlands/CBG • National application for a new active substance: application via the national procedure – **EUR 43,900** • Consultation procedure for medical devices: new use of a medicinal product in a medical device – **EUR 12,000**	**Sweden/MPA** • Approval of marketing authorisation for medicinal products – **EUR 41,289** • Approval of marketing authorisation for medicinal products through the DCP – **EUR 10,332** • Scientific advice – **EUR 4,645**
Malta/MS • New active substance DCP or MRP – **EUR 140,000** • Scientific advice – **EUR 2,300**	**Austria/AGES** • Authorisation in a decentralised procedure for a new active ingredient – **EUR 50,250** • Scientific Advice (for new active substances) – **EUR 8,844**
Slovenia/JAZMP • National procedure (Art. 8(3), Art. 10b of Directive 2001/83/EC) – **EUR 5,000** + **EUR 1,000** for each additional strength and/or pharmaceutical form	**Spain/AEMPS** • Fee for the evaluation, authorisation and registration of a new medicine for human use (application in accordance with Art 17, with the exception of the provision in 17.3) – **EUR 20,734.46** • Fee for the evaluation, authorisation and registration of a new generic medicine for human use (application in accordance with article 17.3) – **EUR 8,434.22**
Portugal/ INFARMED • For each marketing authorisation application regarding a medicine: according to the national procedure (complete) including one strength and one pharmaceutical form – **EUR 2,915.55**	**Poland/URPL** • National procedure – **EUR 19,445**
Ireland/HPRA • An application for one pharmaceutical form in two strengths – **EUR 15,867**	**Denmark/DKMA** • National procedure: new application – **EUR 11,267** • Renewal – **EUR 2,396**

Source: NCA websites

With the above caveats in mind, it appears that a fee for authorisation through the national procedure (for these 10 countries) can vary between EUR 43,900 (NL) and EUR 2,915.55 (PT). Not all of the 10 countries clearly list a fee for a national procedure application (e.g. Malta. However, the NCA clearly states the application cost of authorisation through the decentralised procedure and/or mutual recognition procedure).

As the NCA fees for a marketing authorisation application through the national procedure varies so markedly, calculating a reliable average, which also takes into account the services provided in each case, is difficult. However for the purpose of having a concrete (albeit ball park) figure, we have calculated an average using the fees quoted for a new application for a human medicine using the national procedure in the Netherlands, Sweden, Spain, Poland, Ireland and Denmark (thus leaving out any 'extreme' low or high fees which may disrupt an approximate average). This gives us the figure of EUR 25,417 per application to use as a theoretical average. Thus, should Scenario 2 become a reality, this is (simply calculated) the level of fees pharma companies might face per country. In order for an application to submitted in all 28 EU countries, the total fee would amount to EUR 25,417*28 = EUR 711,676

– or 2.6 times the current EMA fee. EMA charges a fee of EUR 278,800 for a marketing-authorisation through the centralised procedure. Once granted by the European Commission, the centralised marketing authorisation is valid in all EU Member States as well as in the EEA countries Iceland, Liechtenstein and Norway.

It should be noted that these calculations do not take into account additional resource costs faced by the pharma industry if required to prepare multiple applications (in multiple languages). Nor does it take into account any potential discounts available to SMEs.[44]

EMA handled 113 pre-authorisation applications in 2015. Simplifying the calculations, we assume that these applications were submitted along with the fee of EUR 278,800 each, making the total amount charged by EMA EUR 31,504,400.[45]

These calculations only relate to a small proportion of EMA's work. Indeed, in 2015 EMA's income totalled EUR 304,118,788 of which 83.1% stemmed from the evaluation of medicines and other business-related activities. If we therefore apply the 64% increase across all of the relevant activities, the total additional costs would amount to EUR 414,465,249 (83.1% of EUR 304,118,788 = EUR 252,722,713 x 1.64). Thus, in practice the additional costs under Scenario 2 are likely to be around EUR 414 million although certain savings in costs might also be made. An increase in costs of this magnitude could lead to pharma companies increasing prices for their products and services. Finally, it should be taken into account that efficiency gains resulting from a centralised approach (as is currently undertaken by the EMA) in terms of resource savings – both from a human and financial perspective – and pooling of the best expertise at EU level (and not available in each Member State) provide an important contribution to better and timely access to safe and innovative medicines for all EU citizens.

4.1.4 ECHA

Assuming the core principle of one registration per one substance underlying REACH is retained EU Member States would have to agree between themselves who will be responsible for registration and the chemicals data base and various other ECHA activities that were not carried out before ECHA came into existence. It is probable that one or a few of the larger chemical producing Member States would have the capabilities for doing that (or they could share the tasks between themselves).

It is unlikely that mini-versions of ECHA would be replicated across all EU Member States. However, in the absence of an EU contribution a pro rata formula for Member State contributions would have to be agreed to fund the new structures. Another financing option would be to increase fees paid by companies. At the same time, individual Member State would have to increase staffing and resources at their relevant ministries to deal with matters that had been dealt with previously by ECHA. In this Scenario 1 situation, there would be very little, if any, reduction in current costs as a result of transferring the Agency's activities to the Member States. However, there would be increased inefficiency and costs due to the loss of the benefits of concentration and economies of scale and scope. NGOs would also have to

[44] We can also calculate approximate costs by using existing national fees as examples:
1. If we take the Polish fee of submitting a new application through the national procedure as an example then a pharma company that wishes to market its new medicine throughout the EU would need to pay EUR 11,267*28 (= EUR 315,476) or in other words, the cost of the EMA fee would be the equivalent of authorised use in 14.3 countries (EUR 278,800/EUR 11,267 = 14.3) or just over half of the EU Member States.
2. Taking the equivalent Swedish fee as a comparator in this theoretical exercise, a new medicine would reach the market is only 6.75 countries (EUR 278,800/EUR 41,289 = 6.75) if paying the fee of a Swedish authorisation. Should the application be submitted in all 28 Member States, then the cost would exceed that of EMA's fee by EUR 877,292 (EUR 41,289*28 = 1,156,092-278,800=877,292).

[45] Should our theoretical average fee apply instead, the amount due to the NCAs by the pharma companies submitting applications would total (EUR 711,676 x 113 = EUR 80,419,388. This constitutes an increase of EUR 48,914,988 (for the year 2015).

increase their operating costs to deal with more decentralised institutions. We have assumed that there would be an overall 10% increase in costs to Member States compared with the existing situation.

In Scenario 2, where the absence of ECHA as an impartial standard-setter and harmoniser could lead to the emergence of differing chemicals regulatory jurisdictions within the EU, even if not for all substance, and this could lead to substantial cost increases for both public administrations and firms and fragmentation of the Single Market. It would require the establishment of a parallel regulatory apparatus within the relevant Member State(s) and for the firms in question it would imply duplicated costs of testing, registration, and other procedures. Given that the full cost of registering a chemical substance could be EUR 1 million, assuming tis would have to repeated, the sums could quite easily become substantial. In addition, businesses would have to produce, ship and dispose of substances in a fragmented market – at risk of prosecution if substances from one regulatory jurisdiction were sold in a market from a different jurisdiction, either on their own or as part of a different product.

In sum, given that under the REACH Regulation (as well as Biocides and PIC) certain activities have to be performed, and a good many of these were not performed before the Regulations were promulgated, even if there is no ECHA these activities would have to continue to be carried out. So there is little scope for cost reduction, except possibly in terms of improving organisational efficiency and effectiveness. The changes of such improvements are greater in a centralised organisation benefiting from economies of scale than from a spatially distributed organisation(s), where the possibilities of inefficiency and cost increases, subject to the vagaries of public sector funding cycles, are much greater.

4.1.5 EBA

Under Scenario 1, each Member State would have to invest in additional resources to carry out the tasks currently carried out by the EBA. This would probably not involve setting up new entities but rather increasing the personnel in existing government departments, central banks or financial supervision entities.

The 29 officials currently working at the EBA would probably be transferred back into their national administrations. But given the complexity of tasks in question, Member States would almost certainly have to recruit additional staff to handle the additional workload. Overall, we estimate that the net effect of increased staff and communication needs under Scenario 1 would lead to a higher overall cost but that this would be counterbalanced by lower rates of pay for staff and establishment costs because of no longer being London-based. There would, however, be increased costs associated with liaison between the national authorities in different Member States. So, overall, the costs of a Scenario 1 would remain at close to the current levels of EBA costs of about EUR 30 million, but with losses in efficiency and effectiveness.

Under Scenario 2, where the absence of a central supervisory body leads to the emergence of different regulatory standards between jurisdictions (i.e. no Single Rule Book), Member States would still be in the Scenario 1 situation but multinational financial institutions would have to incur additional costs to comply with the different national rules. It is not possible to estimate the increase in costs to financial institutions but there would of course be a negative effect on the development of the Single Market.

4.1.6 ESMA

Under both scenarios, there would be initial cost savings in the EU budget and national budgets. The EU budget would save EUR 10.2 million in current contributions to ESMA's budget p.a. and Member States would save EUR 16.86 million in contributions (an average of EUR 600,000 p.a. per Member State). In practice, most Member States would probably increase

capacity internally rather than creating a new national entity to deal with the increase in work to be carried out under both scenarios.

In the following, we estimate the average additional cost to each Member State if the current staff and expenditure of ESMA (see Table 5 on page 27) were divided amongst the 28 Member States. In estimating cost changes, it is useful to distinguish between supervisory activities, for which ESMA charges fees to market users, and the other activities.

Beginning with supervisory activities, ESMA currently charges fees in the order of EUR 9.75 million per year to market users for its services. This function affects 11 Member States in which 40 Credit Rating Agencies (CRAs) currently supervised by ESMA are based. If ESMA did not directly supervise these CRAs, then the NCAs in the 11 Member States concerned would have to take over this task. In each of these Member States, an average of 3.6 CRAs would have to be supervised. At present, ESMA allocates an average of 1.2 FTE per CRA[46] it supervises. However, due to the complexity of these supervisory activities, requiring risk, legal and IT experts as well as Independent Investigator Officers, even the supervision of a small CRA would probably require a minimum of 3 members of staff, or 3 FTE at Member State level per CRA. Multiplied by the average of 3.6 CRAs per Member States, this means that each of the 11 Member States would have to pay for an average of 10.8 FTEs for supervisory activities under both scenarios – an increase of 300% compared to the status quo.[47] NCAs might be able to limit the additional cost arising from this activity provided they are able to charge an equivalent fee per agency as ESMA currently does. But this would only cover part of the additional cost given the higher number of staff required at national level compared to at ESMA.

With regard to the other activities carried out by ESMA, we have assumed that in each of the 28 Member States, the NCAs would have to take over the activities set out in the table below. One caveat is that the first activity of promoting supervisory convergence encompasses the development of shared IT systems (for example, on MiFID II implementation). Before setting this up, ESMA calculated the costs of each Member States developing these systems independently compared to ESMA developing it for all Member States together. In case of the MiFID IT project they estimate the cost to be 10 times higher if Member States developed this on their own. This means that the values in the first row of the table below probably underestimate the additional cost to Member States and hence need to be viewed as a minimum estimate.

Table 7: Cost to Member States

Activities[48]	Human resources per MS in FTE (avg.)	Financial resources per MS in million EUR (avg.)
Promoting supervisory convergence	3.6	0.62
Assessing risks to investors, markets and financial stability	1	0.16
Completing a Single Rulebook for EU financial markets	1.1	0.18
TOTAL	**5.7**	**0.96**

[46] 40 agencies divided by 11 Member States

[47] Moreover, those Member States in which the four third country CRAs are based would have to supervise those and charge them fees accordingly.

[48] These figures are based on ESMA's projections and are in line with the MFF. Both administrative and support staff are included in the table. Please note these figures include the allocation of Temporary Agents + Contract Agents + Seconded National Experts whereas the MFF provides indications only on Temporary Agents.

As the table shows, each Member State would have to allocate an average of 5.7 additional staff and EUR 960,000 to cover additional tasks (other than direct supervision) to replace ESMA. However, this needs to be looked at in context of the cost savings of EUR 600,000 per Member State, meaning that the cost increase would likely only amount to EUR 360,000 per Member State. While this may seem rather insignificant, the actual additional cost would likely be significantly higher, as outlined below.

Under both Scenarios, training costs would increase as each national authority would have to carry out its own training programmes while currently ESMA runs programmes open to all national authorities. Data collection would be decentralised again, driving up costs. Governance and translation costs would increase as projects initiated by ESMA such as the development of joint IT systems and databases would cease to exist.

As regards Scenario 1's wider effects, there is inconclusive feedback from stakeholder as to the change in cost, making it difficult to provide a quantitative estimate. Factors determining the cost change include the resources already currently allocated by each NCA to supporting ESMA's work (which most likely varies by Member State) and the degree to which NCAs do or do not have in-house capacity to supervise and develop the complex set of EU regulation now overseen by ESMA themselves, and which would remain in place under this Scenario. The cost of Scenario 2, in turn, would be determined by the response of each individual Member State if ESMA ceased to exist. This would depend on national priorities, size of domestic financial markets and the types of entities operating within them.

Finally, the cost to market users of Scenario 2 in particular could be very considerable although not possible to quantify. The cost of a potential financial crisis due to reduced market supervision might be very significant to the economy. Looser cooperation between NCAs on the basis of mutual recognition could lead to inconsistent application of rules for financial market participants, contributing to regulatory and supervisory arbitrage, disintegrated financial markets and lack of supervisory information on cross-border activities within the EU. The cost of instable financial markets would be much more significant than any change in the level of fees levied to CRAs or any cost savings due to reduced regulatory requirements.

4.1.7 EIOPA

In a Scenario 1 situation the activities carried out by EIOPA would be taken over by Member States. On balance it is unlikely that the numbers and costs of staff required would change significantly, although the loss of scale economies and the other benefits of an independent European body (as outlined below) would counteract reductions in overhead costs from closing the Agency.[49]

EIOPA promotes the exchange of information between the NSAs and has a key role in helping to ensure effective supervision. With the Single Rulebook for reinsurance and insurance companies in place, EIOPA will receive data from companies throughout Europe, creating a centralised database which allows the development of reliable risk analysis and early warning indicators at individual, group and system-wide level and provides the NSAs with peer group comparisons, increasing supervisory capabilities at a national level. This will reinforce the quality of both micro- and macro-supervision in the EU. The building up and maintenance of this database could only be done by an independent and coordinating body such as the EIOPA.

[49] In the absence of a central location for meeting, discussion, and research, more travel and communication activities would be required by national officials and private sector stakeholders in order to exchange ideas and discuss positions to formulate common standards. This could incur additional costs and delay decision-making. As such, the costs of undertaking EIOPA tasks at the national level would probably not reduce below the level of EUR 20 million that it currently costs to operate the Agency (see Table 6 in Section 3.3.7).

Another task which can only be carried out by an independent European entity such as EIOPA is enforcing supervisory convergence. In a Single Market, where cross-border business plays an increasing role, it is fundamental to ensure that the supervisory system has no weak links. This entails a common European supervisory culture, meaning the development of common ways of thinking, behaving and working. This implies a common interpretation of laws and regulations in view of good and effective supervision. EIOPA has been undertaking this challenge by contributing to a Single Handbook for the NSAs, building on a common database, monitoring internal models and using stress estimations to assess risks and vulnerabilities throughout the market. An independent engagement with all the NSAs to give challenging supervisory feedback and support to improve national supervision has proved effective. Only an independent authority can fulfil this function. This also allows targeting issues that go beyond one national market, building coordinated understanding.

The global nature of insurance means that to promote stability there should be a global group solvency regime that is applied by all jurisdictions. In this respect, EIOPA has had an important role in representing the EU in the international body IAIS, specifically in relation to its work streams on international capital standards, building on the Solvency II framework and the progress made in incremental convergence at a European level.

If Scenario 2 were to occur, the establishment of new agencies in at least some Member States would of course involve additional costs. However, the main cost driver would be if the supervisory systems did not include mutual recognition and as a result there was a need for a country by-country ratification and approval procedure. In addition, it is unlikely that the scale of regulatory activity in many smaller Member States would justify the levels of expertise and specialised capabilities on a purely national basis that are currently accessible from the EIOPA.

4.1.8 Conclusions

Overall, our research suggests that there would no net financial gain if the seven EU agencies ceased to exit. Indeed, although there would be an initial saving of approaching EUR 1 billion (2015) in the seven agencies' operating costs (or of EUR 78m in net terms of the EU budget), this gain would almost certainly be outweighed by a subsequent increase in other costs to national authorities and to industry.

In particular, in most Member States the national authorities would have to either expand existing entities or establish new ones to take on tasks previously handled by the EU agencies. Likewise, in the case of the EUIPO, EASA, EMA and ECHA, companies would probably have to pay higher fees and charges than at present to obtain EU-wide IP protection, and the necessary certification of products and services to be able to trade in markets across the EU Member States. In the case of the three financial supervision agencies, the costs to Member States from taking over their functions can be estimated but the financial consequences for financial sector undertakings are impossible to quantify.

4.2 COST OF NON-AGENCIES' TO KEY STAKEHOLDERS

Below we examine the 'cost of non-agencies' to national authorities, end-users of the agency services and to the European Commission.

4.2.1 National authorities

Under Scenario 1, the **EUIPO, EMA, EASA** and **ECHA** functions (apart from those that might be transferred to the Commission – see below or that would be discontinued) would be taken over by the Member States. In some cases, existing national entities might have the capacity to take on additional functions but otherwise the transfer of EU agency functions would involve either setting up new entities or expanding existing ones. The costs to different Member States could of course vary. For example, some countries could decide not to set up

their own agencies but instead to place themselves under the jurisdiction of a national entity in another country.

In the case of the three financial regulatory agencies, the **EBA, ESMA** and **EIOPA**, in some cases national entities already exist that could take over their tasks at a national level but in other cases, there could be considerable costs in developing the necessary capacity. For all Member States, there would also be significant additional costs in cooperating bilaterally to share know-how and to develop common tools. This type of collaboration would probably not, however, extend to developing the type of EU-wide supervisory functions currently exercised by the various agencies as national agencies would not be empowered in this way.

Overall, under Scenario 1 there could be an estimated additional cost to national authorities of around EUR 150-200m p.a. compared with the cost of the seven EU agencies (2015). If mutual recognition were to be eroded (Scenario 2), more EU Member States would have to set up their own structures to deal with certification of products and services, and others would have to expand these functions. These additional costs cannot, however, be estimated.

Some Member States would also be adversely affected by the closure of EU agencies located in their countries (see Table 1 on page 5). In total, some 3,500 jobs[50] in the seven agencies could be either lost or transferred from the host countries to other locations (e.g. Brussels). In addition to the direct job losses, there could also be significant indirect employment effects. For example, each of the agencies hosts meetings and other events attracting considerable numbers of visitors to the cities where they are located throughout the year. Although not possible to quantify, the indirect jobs supported by this agency-related business in the hospitality sector (hotels, restaurants, local transport, etc) and other parts of the local economies is likely to be quite significant.

The net position at the EU level would be broadly neutral with some locations (e.g. Brussels) benefiting from the employment opportunities transferred from the locations where the agencies are presently located. Similarly, if the EU agencies ceased to exist, some new job opportunities could be created in the entities in the same countries that would be created or expanded to replace them. However, for some of the current locations (particularly the smaller cities), the effect of the 'non-agencies' scenario would not be mitigated by these compensating factors.

4.2.2 Companies and other end-users

Under Scenario 1, the costs of obtaining certification of products and services would probably remain more or less the same in the short-term, although there is some variation between agencies[51]. However, in the medium-term the question is the extent to which the fees that would be charged by national agencies would differ from those currently charged if the national agencies delivered the services without the involvement of the EU agencies.

This assumes that the EU regulatory framework remains in place and obligations on Member States do not change and that national agencies would be empowered to issue EU wide IP rights (**EUIPO**) or registrations (**EASA**, **EMA** and **ECHA**). Under Scenario 2, the regulatory framework might stay in place but mutual recognition could be eroded by differing interpretations of the framework and/or its partial enforcement. In this situation it might be necessary for companies and other end-users to deal with up to 28 different national

[50] In the case of the EUIPO, an external study conducted by Deloitte in 2016 estimates that the Agency boosts GDP in the Valencia region by EUR 323 million and maintains some 2,600 jobs in the regions.

[51] The costs to companies and end-users of transferring the EUIPO's services to Member State bodies would immediately increase significantly (see section 4.1.1).

authorities. If this became necessary, the fees and charges required to obtain the same EU-wide rights and registrations would be much higher than is the case at present where these can be obtained through one application procedure at the EU level. In addition, the internal costs to companies in staff time and other resources of obtaining multiple registrations and certifications would be considerable. These company costs would be even higher (but impossible to quantify) if goods and services had to be adapted to different markets.

In the case of the **EBA**, **ESMA** and **EIOPA**, their activities related to the market cannot be characterised as services as they benefit all economic operators in the financial services sector and as such no operator can decide to 'opt out' from benefitting from these services. In a sense, they have more in common with public goods than with outputs that national competent authorities (NCAs) or private sector stakeholders. In this sense, there would be very little difference between the Scenario 1 and Scenario 2 situations in terms of the effect on financial services operators.

In conclusion, whilst under Scenario 1 there would in most cases be no significant change in the costs to companies and other end-users, at least in the short-term, with Scenarios 2 where there could be considerably higher costs. We estimate these costs to be up to 1bn p.a. more compared with the existing EUR 947 million pa. (i.e. EUR 1,025 million operating cost of agencies less EU grant of EUR 78 million).

In relation to the EBA, ESMA and the EIOPA, there would be no direct 'cost of non-agencies' to companies because these are not clients of the agencies but indirectly there could be significant impacts arising from less well-regulated financial markets. These additional costs cannot be quantified.

4.2.3 European Commission

Under Scenarios 1 and 2, there could be an annual overall saving of EUR 78 million (2015) to the EU budget subsidy to the seven agencies. However, because the EU subsidy helps to cover the cost of providing EU policymakers with the information needed to take decisions and to monitor the enforcement of regulations, it is likely that this activity would be transferred to the European Commission if the agencies ceased to exist with little or no net saving.[52]

Moreover, the capacity of the Commission to take on the full range of agency functions could be quite limited. With the Commission affected by the same budgetary constraints as the agencies, there would be little or no scope to recruit new staff. Instead, the most likely course of action is that there would be a transfer of some of the personnel from the agencies. The Commission would probably also have to take over some other activities, for example the representative functions at an international level for the issues currently handled by the seven agencies, and there would be some additional costs of doing this.

Under both Scenarios 1 and 2, the cost implications to the Commission of the seven agencies ceasing to exist would be more or less neutral. There would probably be no saving from terminating the EUR 78 million annual grant (2015) to the agencies as this would be offset by higher costs to the Commission as a result of transferring personnel from the latter to the former so that services relating to policymaking, the international representation and other EU level tasks are continued.

[52] In the case of the ESAs, it would not be possible for the Commission to take over their responsibilities completely. The ESAs have a different membership status within international bodies (Basel Committee, IOSCO and IAIS), whereas the EC is only an observer.

4.3 OTHER COSTS OF 'NON-AGENCIES'

In addition to the cost-savings highlighted in the previous section, the seven agencies result in other benefits which would be lost if they ceased to exist.

First and foremost the seven agencies have an important role in helping to ensure the efficient functioning of the Single Market and without them this would be more difficult with consequent wider negative effects both politically and economically. In the case of the EUIPO, EASA, EMA and ECHA this role has direct benefits and cost-savings for companies (partially quantified in the previous section) which, in turn, has wider positive effect on the European economy as a whole in terms of competitiveness, innovation and, ultimately, in terms of enhanced growth, job and wealth creation. Just the REACH Regulation is expected to provide several billion euros worth of benefits to health, safety and the environment. Should the Regulation not be implemented appropriately these would be at risk. Moreover, the sectors concerned – pharmaceuticals, aerospace, chemicals and biotechnology, and the knowledge economy in general – are key enabling technology sectors strategically vital to the EU. In relation to the EBA, ESMA and EIOPA, it is difficult to quantify the benefits of enhanced supervision and of the role of the agencies in helping to avoid another financial crisis or protecting providers and users of financial services. There are also cost savings (equally impossible to quantify) to financial sector companies from having to only comply with a harmonised / common set of rules instead of having to deal with 28 different EU Member State rules.

Secondly, a centralised repository of expertise and knowledge in relation to seven key sectors of the European economy would be dispersed and more costly to retrieve if the agencies ceased to exist. The agencies provide a coordinated mechanism at the EU level for developing and sharing technical know-how. This is achieved through networking, joint research, developing tools to address common challenges, etc. The EMA, for example, coordinates a network of more than 4,500 experts in Europe who are available to help NCAs to undertake the assessment of new human and veterinary medicines. Likewise, in the case of the EUIPO, expertise that has been accumulated since the establishment of the Agency two decades ago would be dispersed and would lead to additional costs arising from a loss of scale. ECHA holds and updates the central data base of the EU's chemicals substances. EBA is the key source of knowledge for linking the EU to global banking regulation through Basel III. As things stand now, the pooling of expertise in these and other fields at the EU level means that the best know-how can be mobilised to tackle the challenges faced by Member States. The EBA, ESMA and EIOPA have a similar function in relation to the regulation of financial markets, specifically through the development of the Single Rulebook.

Related to this, the data that is collected by the agencies from across the Member States is also important in informing decisions by companies, national authorities and policymakers at the EU level. For example, in the case of ESMA there are around 200 organisations (trading venues, CRAs, TRs and national authorities) that report on an ongoing basis to data repositories created and managed by the agency. Similarly, the EUIPO manages a large database register of European trademarks and designs containing 1.3 million EUTMs and 700,000 RCDs. It is also responsible for the Orphan Works Database[53]. The EMA's EudraCT database provides useful information on ongoing clinical trials in Europe with alerts in case of early interruption or termination. Systems such as this would be much more difficult – and costly – to maintain in the absence of the coordinating function undertaken by the agencies.

[53] The Orphan Works Database provides information related to orphan works contained in the collections of publicly accessible libraries, educational establishments and museums, as well as archives, film or audio heritage institutions and public-service broadcasting organisations established in the Member States.

Thirdly, the seven agencies have an important role in coordinating the EU's position internationally on issues relating to their areas of responsibility and this would be more difficult without them. For example, EASA works at facilitating the free movement of European products and services worldwide. It assists non-European authorities when they certify European products and services. Reciprocally, it issues European certificates for non-European products. The agency also works with the European Commission and EASA Member States, and has a role in relation to IATA, to coordinate common positions on matters of global nature. Likewise, the ECHA shares experience with an increasing number of regulatory authorities in countries adopting chemicals safety legislation similar to REACH, CLP, Biocides and PIC Regulations. When it comes to the EUIPO, it has an essential role in supporting the EU's intellectual property infrastructure and enforcement, which in turn benefits the EU economy and society as a whole. Its close cooperation with the major international IP bodies is also key in harmonising and improving global IP protection and procedures.

Similarly, ESMA's international work has seen it focus on equivalence assessments, developing and concluding cooperation agreements, as well as preparing for the extension of the Alternative Investment Fund Managers Directive (AIFMD) passporting regime.

It is conceivable that some of these functions could be undertaken internally by the European Commission. However, this would almost certainly not produce any cost savings.

4.4 SUMMARY - COSTS OF NON-AGENCIES

AGENCY	SCENARIO 1	SCENARIO 2
EUIPO	Existing IPOs in certain countries (DE, ES, FR, IT, UK) would take on most of the post EUIPO IP registration tasks (some 70%) with additional costs estimated at EUR 81.5 million (EUR 16.3 million x 5). If the value of losing the EUIPO's other services is also counted, a further EUR 102 million should be added (IP collaboration: EUR 71.1 million and Observatory: EUR 31.1 million).	National IPOs have lower charges for trademarks than EUIPO but companies would have to register separately in several countries so costs would be much higher (EUR 349 million (14 Member States) to EUR 698m (28 Member States) compared with EUR 116.2 million using EUIPO in 2015).
EASA	The NAAs in three countries (DE, FR, UK) would probably take on most of the EASA tasks and would need to expand their capacity. We have assumed that there would be a 10% increase in net costs compared with the current EASA costs.	Instead of the current cost to industry of EUR 91 million for EASA certification and other services (2015), the cost could increase threefold to at least EUR 300 million to the aviation industry if it was necessary to certify products via at least three NAAs.
EMA	Existing NCAs would take on EMA tasks. As the cost of processing applications is incurred already at the national level, any increase in the volume of work would probably be covered by a larger fee-based income. We have assumed a 10% increase in costs for Scenario 1.	EMA fees and charges related to marketing authorisations amounting to EUR 255 million (2015). The additional costs under Scenario 2 are likely to be around EUR 414 million although certain savings in costs might also be made. An increase in costs of this magnitude could also lead to pharma companies increasing prices for their products and services.
ECHA	One or a few existing organisations in key countries would take over ECHA activities, funded by Member State contributions and fees received. Additional staff would be required at the Member State level. We have	Same as Scenario 1 except emergence of new chemicals legislation jurisdictions requiring enterprises to register there as well. In addition to EUR 117 million under Scenario 1, there could be a conservative EUR 8 million

AGENCY	SCENARIO 1	SCENARIO 2
	assumed a 10% increase in costs to cover additional personnel recruitment.	per jurisdiction under Scenario 2, i.e. up to EUR 224 million overall in additional costs.
EBA	National entities would take over activities of EBA. Costs would be reduced due to no longer operating from a London base but additional staff and communication needs would mean that the overall costs would probably remain the same at EUR 33 million.	If separate banking jurisdictions emerge within the EU due to differences over implementation of CRDIV and CRR, this would add costs for national competent authorities but in particular for private banks. It is not possible to quantify the additional costs.
ESMA	National entities would take over the activities of ESMA, increasing capacity in national competent authorities. The costs of this could amount to around a combined EUR 10 million across EU28 Member States.	Cost to market users could potentially be extremely high if reduced supervision and regulation leads to market instability. However these and other costs, including direct costs to companies, of Scenario 2 cannot be quantified.
EUIPO	Member States would continue with the activities together with additional co-ordination activities for interaction between Member States. The net effect of Member States continuing the EIOPA's work would be that the regulatory framework and its enforcement would break down and erode.	If Scenario 2 were to occur, with the establishment of new agencies in at least some Member States, there would be additional costs. However, the main cost driver would be the breakdown of the joint supervisory systems and as a result there was a need for a country-by-country ratification and approval procedure. It is not possible to quantify the additional costs.
Overall	**There could be EUR 150 million to 200 million in additional costs arising from the need to recruit additional staff at the Member State level to take over the EU agencies' tasks. In most cases, existing entities would take over these tasks although some Member States might rely on others to provide the services previously delivered by the EU agencies.**	**Additional costs from the need to register products in a number of Member States could amount to an additional EUR 1 billion compared with the current costs depending on how many Member States companies would registered their products in separately. This does not include the internal costs to companies of multiple certification and registration requirements. The additional Scenario 2 costs in the case of financial supervision agencies are unquantifiable.**

5 CONCLUSIONS

In relation to the three objectives of this analytical study (see Section 1), the overall conclusions are summarised below:

The key objective of this study was to estimate the impact on the EU budget and national budgets of the creation of the EU agencies and addressing their respective tasks at the European level rather than alternative solutions at the national level. **The research suggests that it is considerably less costly to carry out the tasks assigned to the agencies at the EU level than it would be if these tasks were undertaken by the EU28 Member States.**

In 2015, the cost of operating the seven agencies was a combined EUR 1,025 billion. However, the cost to the EU's budget was much lower than this (EUR 78 million) because most of the revenue (some 93%) required to cover the cost of operating the seven agencies came from fees and charges that were paid for by public and private sector organisations in the Member States. The extent of dependence on EU funding varies with the three financial supervision agencies (EBA, ESAM, EIOPA) being more dependent on grants and the other four agencies (EUIPO, EASA, EMA and ECHA) being less dependent. Two agencies (the EUIPO and EMA) do not rely on funding from the EU budget at all.

According to our best estimates, if the Member States took over the functions of the seven agencies, the additional costs to national authorities would be around EUR 150 million to EUR 200 million (p.a. based on 2015 data). There would be no net saving therefore from a reduction in EU funding to the agencies but rather a net increase of around EUR 72-122 million p.a. (EUR 100-2000 million less EUR 78 million). This additional cost would arise from the need to either expand existing national agencies or to create new entities to take on the tasks previously carried out by the EU agencies. The financial implications would not of course be the same across the EU Member States. For example, some Member States might decide, because of a lack of capacity or lower demand from companies, to rely on the services provided by agencies located in other countries.

However, the most significant potential impacts arising from a 'non-agencies' situation would be on companies seeking to trade across the EU28 Member States in the Single Market and on the stability of Europe's financial system.

If the seven EU agencies' tasks were transferred to the Member States but the EU regulatory frameworks remained in place, the effects on companies seeking to register or certify a product or service would probably be quite modest (although the ending of a common EU-wide system of fees and charges could in some cases lead to increased costs). However, the most significant financial implications would arise in what we have described as a "Scenario 2" situation, i.e. where a lack of EU-level enforcement and monitoring by the agencies leads to the EU regulatory framework being interpreted differently across the Member States or only being partially applied. Under these circumstances, mutual recognition would be eroded resulting in the possibility that companies would have to seek certification or registration of products and services in up to 28 different countries. In reality, national entities in a small group of Member States with the necessary capacity and expertise might take over the tasks currently undertaken by the agencies on behalf of a wider group of countries. Nevertheless, even in this situation, the costs would be considerable.

Although it is extremely difficult to estimate, our analysis suggests that the additional costs to European companies of Scenario 2 situation could be around EUR 1 billion depending on the extent to which it would be necessary to register products and services separately in different Member States (this would depend on the extent of mutual recognition but also on how extensively companies trade across the EU). Moreover, there would also be 'hidden' costs, i.e. the internal costs to companies of having to

carry out multiple certification and registration requirements, and of possibly having to adapt goods and services to different national standards. The additional Scenario 2 costs in the case of financial supervision agencies are unquantifiable but lie in helping to maintain the stability of the EU's financial sector and financial markets. There are also other costs of 'non-agencies' (efficient functioning of the Single Market, the role of the agencies in international cooperation, etc) which can only be assessed qualitatively.

It should be stressed that it is difficult to quantify costs precisely because there are many 'unknowns'.

In relation to the third study objective, establishing whether the value added is recognised by national authorities, concerned third parties and internationally, the research feedback – as highlighted throughout this report – strongly confirms that added value is widely recognized.

A matter not covered by the current study but presenting certain interest for future research stems from the pattern which can be observed with regard to creation of the agencies: a quite common scenario is that the political decision leading to creation of an agency is triggered by a crisis or by an incident. For instance, European Food Safety Authority (EFSA) was established in 2002 following a series of food scares in Europe (mad-cow disease in 1996 and 2000, dioxins in 1999, etc.)[54]; likewise, the European Maritime Safety Agency (EMSA) was established in response to the 'Erika' oil tanker incident[55]. A proposition can be put forward that the creation of these and other agencies may have prevented or mitigated further incidents and crises in their respective areas. Identifying the cases in which the agencies have played such role, and assessing the long-term savings resulting from prevention or mitigation of incidents or crises could be a topic of a future study.

[54] Food Safety at Stake – the Establishment of Food Agencies, Lise Hellebø
http://www.ub.uib.no/elpub/rokkan/N/N14-04.pdf
[55] Regulation (EU) No 100/2013 of the European Parliament and of the Council, OJ L 39, 9.2.2013, p. 30

APPENDIX A – LIST OF INTERVIEWS

Organisation /MS	Contact name and position
European Parliament	Jens Geier MEP
	Edit Herczog (former MEP)
EUIPO	
EUIPO	Nestor Martinez-Aguado, EUAN Coordination Team
EUIPO	Goran Marjanovic, Project officer, International Cooperation and Legal Affairs (provided extensive written answers)
Irish Patents Office	Dermot Doyle, Head of Trade Marks Examination, Member of the EUIPO Management Board & Budget Committee
Italian Patent and Trademark Office	Simona Marzetti, Head of Division of Intellectual property Promotion and International Affairs
Patent- og Varemærke-styrelsen (Denmark)	Anne Rejnhold Jørgensen, Director of Policy and Legal Affairs (Chair of the EUIPO Budget Committee)
EASA	
EASA	Cluzeau Jean-Marc, Head of Strategy and Programmes Department
EASA	Piero Bortolotti, Planning and Performance Manager
Airbus Group, FR	Yves Regis, vice president of Product Integrity
Dassault Aviation	Gilles Garrouste, Head of Airworthiness
AeroSpace and Defence Industries Association of Europe	Yoann Viaouet, Civil Aviation Manager
Department for Transport, UK	Mike Alcock, Head of Aviation Safety Policy
DG Mobility, NL	Bob Rieder, Senior Policy Officer.
DSAC, FR	Genevieve Molinier, Head of European Cooperation and Safety, DSAC
ENAC, IT	Deputy, ENAC DG, of Mr. Alessio Quaranta
LBA, DE	Dirk Sajonz, Head of Division on National and International Tasks
EMA	
EMA	Anthony Humphreys, Head of Scientific Committee Support Department
EMA	Michael Lenihan, Head of Finance and Budget
EMA	Silvia Fabiani, Management Board & HMA
Medicines and Healthcare Products Regulatory Agency UK	Ian Hudson, Chief Executive
AGES Medizinmarktaufsicht / Austrian Medicines and Medical Devices Agency	DI Dr. Christa Wirthumer-Hoche, Head of Austrian Medicines and Medical Devices Agency
ECHA	
ECHA	Frank Buechler, Team Leader, Executive Office
Ministero dello Sviluppo Economico	Antonello Lapalorcia, Dirigente, Direzione generale per la politica industriale, la competitività e le piccole e medie imprese
Ministry of Infrastructure and the Environment, Netherlands	Hans Meijer, Coordinator chemicals management Directorate for Safety and Risks
Bureau for Chemical Substances, Poland	Jerzy Majka, Inspector for Chemical Substances, Michal Andrijewski MSC

Swedish Chemicals Agency	Lisa Anfält, Head of Unit, EU Co-ordination
Cruelty Free International, European Coalition to End Animal Experiments (ECEAE)	Dr Katy Taylor, Director of Science and Regulatory Affairs, Secretariat to the International Council on Animal Protection in Pharmaceutical Programmes (ICAPPP)
Eurometaux	Violaine Verougstraete, EHS Director
Centre for Chemical Substances and Preparations, Ministry of Economy, Slovak Republic	Miroslava BAJANIKOVA (written)
CONCAWE	Robin Nelson, Science Director
CEFIC	Erwin Annys, REACH Director
EBA	
EBA	Peter Mihalik, Director of Operations
EBA coordination DNB	Olena Loboiko, Joost Passenier, Tijmen Swank
De Nederlandsche Bank Supervisory Policy Department	Olena Loboiko, Joost Passenier, Tijmen Swank, EBA coordination (written)
The Bank of Portugal	Adelaide Cavaleiro, Adviser to the Board of Directors
Federal Financial Supervision Authority, BaFin(Germany	Dr Peter Lutz, Executive Director, Head of Departement SSM supervisory standards (BA1), Banking Supervision
Knf.gov.pl	Andrzej Reich
Bank of England	EU and Global Prudential Policy, Prudential Regulatory Authority (written)
ESMA	
ESMA	Jakub Michailik, Officer in Legal, Cooperation and Convergence Division
ESMA	Mette Filtenborg, Head of Corporate Affairs Department
BaFin (ESMA Competent authority, DE)	Elisabeth Roegele, Chief Executive BaFin Director for securities supervision
EIOPA	
EIOPA	Philip Codrai, Strategy and Institutional Coordination
EIOPA	Danny Janssen, Head of Corporate Support Unit
EIOPA	Susanne Rosenbaum, Counsellor to EIOPA's Senior Management

APPENDIX B – AGENCY REPORTS

Name of Agency	**European Union Intellectual Property Office - EUIPO**
Date created	1994
Legislation	• Council Regulation (EC) No 207/2009 on the European Union trade mark and Commission Regulation (EC) No 2868/95 as last amended by Regulation (EU) 2015/2424 of the European Parliament and of the Council of 16 December 2015. • Council Regulation (EC) No 6/2002 on Community designs. • Regulation (EU) No 386/2012 of the European Parliament and the Council on entrusting the Office for Harmonization in the Internal Market (Trade Marks and Designs) with tasks related to the enforcement of intellectual property rights, including the assembling of public and private-sector representatives as a European Observatory on Infringements of Intellectual Property Rights.
Rationale for existence	The advent of the single market created a need and demand for intellectual property rights that were valid throughout that market. So the Community trade mark (now the EUTM) was created but at the same time he legislators decided, after exhaustive debate, that the specialised nature of this function, the scale and the need for independent legal decision-making merited the creation of a European separate agency. Designs were added on later.
Agency objectives	To offer intellectual property (IP) rights protection to businesses and innovators across the European Union and beyond.
Set up pre-agency	Prior to the creation of the EUIPO, trade mark and design rights within the EU could only be registered on a country by country basis directly with the National IP Offices or via the Madrid and Hague systems for trademarks and designs, respectively, administered by the WIPO.
Main services/ outputs (number & type of clients and their location)	• Registration of EU trade marks (EUTM) and registered Community designs (RCD) – 130,400 EUTMs and 97,500 RCDs registered in 2015 – 69% of which to EU businesses and innovators, 31% to non-EU users. 99% of all trade mark and design applications are made online. In total, there are nearly 1.3 million trademarks registered with the EUIPO. • Harmonisation of registration practices and development of common tools in cooperation with IPOs in EU28, users and other institutional partners within the European Trade Mark and Design Network (ETMDN) to offer users a similar registration experience, be it at national or at EU level. • Hosting the European Observatory on Infringements of Intellectual Property Rights which brings public and private stakeholders together in the fight against piracy and counterfeiting. • Management of the Orphan Works Database
- **Public sector**	• Intellectual Property Offices (IPOs) in the EU Member States. • European Commission • EUROPOL, CEPOL, EUROJUST • IP offices in 37 non-EU countries
- **Private sector**	At present, the EUIPO trade mark system has **410,124 EU users** owning at least 1 EU trade mark still in force, out of 500,500 users world-wide and Legal entities make up 75.5% of all users and individuals 24.5%. The main EU users are Germany (86,839=21.17%), UK (58,422), Spain (57,329), Italy (52,511) and France (36,007), accounting for 71% of all users.
- **NGOs**	n/a

- **Wider**	Close cooperation activities within TM5/ID5 – the world's five leading trade mark and design office USPTO (US), JPO (Japan), KIPO (Korea), SAIC/SIPO (China) & EUIPO
Resources (2015)	
- **Staff**	848 staff (785 statutory officials, temporary agents, contract agents & 63 seconded national experts).
- **Financial**	Budget 2015: EUR 384.2 million Revenue (2015) from EU Trade Mark fees: EUR 188,691,789 Revenue (2015) from RCD Design fees: EUR 23,869,252
- **Fees and charges for using services (if relevant/ available)**	**EUTM applications**: 1 class goods/services: EUR 850, 2nd class: EUR50, 3rd class: EUR 150 = Total fee 3 classes: **EUR 1.050** (when filed electronically) **RCD applications**: 1 design: **EUR 350**, 2nd-10th design: EUR 175 each, >11th design: EUR 80
Potential future development	The Agency is considered by users to be an effective and successful body which has stood the test of time and the Agency's regulatory framework was just reformed and modernised in December 2015, which would be a good indication that EU institutions and users are keen to see the Agency continue its good work.

Name of Agency	**European Aviation Safety Agency - EASA**
Date created	2002
Legislation	**Regulation (EC) No 216/2008 of 20/02/2008** on common rules in the field of civil aviation and establishing a European Aviation Safety Agency
Rationale for existence	The Basic Regulation establishes common requirements for the regulation of safety and environmental sustainability in civil aviation. The Agency answers the Regulation's need for 'a single specialised expert body', which delivers appropriate expertise to EU institutions to prepare these rules and verify their implementation at national level. Thus the Agency acts as an enabler to the legislative and executive process, a body which 'is independent in relation to technical matters and has legal, administrative and financial autonomy.' There were further reasons behind the creation of a Community Agency. Past experience has suggested that common rules do not ensure uniform implementation in domains where technical discretion must be given to the certificating entities. In such cases the centralisation of certification tasks is the only effective way to achieve the desired uniform level of protection. This option was strongly supported by all interested parties. It also ensures that safety-related measures remain free of any political interference which might prejudice the current high standard of civil aviation safety enjoyed in Europe.
Agency objectives	EASA's mission statements are: • Ensure the highest common level of safety protection for EU citizens. • Ensure the highest common level of environmental protection. • Single regulatory and certification process among Member States. • Facilitate the internal aviation single market & create a level playing field. • Work with other international aviation organisations & regulators.
Set up pre-agency	Voluntary cooperation between some EU and non-EU member states under the Joint Aviation Authorities (JAA), widely seen as weak and ineffective at implementing common safety regulations. NAAs worked more or less independently.
Main services/ outputs (number & type of clients and their location)	Main activity is certifying products in civil aviation for the European airspace. EASA manages most of the certification activities, with the remainder being outsourced to NAAs. Other activities include rule making, providing technical training and research. EASA also works internationally providing technical cooperation with third countries with funds allocated by the Commission.

- **Public sector**	National Aviation Authorities (NAA) of EASA's 31 Member States. They, along with producers and consumers of the civil aviation market in Europe, are the main beneficiary.
- **Private sector**	The EASA facilitates the civil aviation market in Europe. Any organisation which wishes to operate or use a product within the air space of the EASA's Member States must comply with the agency's certification and standardisation process. Services are provided to both EU and non-EU companies; organisations require certification and products (i.e. anything that flies) must undergo a standards check. The EASA's services have a global reach to private sector companies given the unique, globalised nature of civil aviation; all international traffic flying into the EU including supporting aspects (mechanics, crews etc.) fall under the EASA's competencies. The EASA has a close relationship with European private sector companies in the aviation sector such as Airbus Group, Dassault Aviation etc.
- **NGOs**	Not applicable.
- **Wider**	EASA works with other international regional aviation bodies (including Chinese and U.S counterparts) to harmonise regulations of air worthiness and develop working agreements and mutual recognition agreements. EASA reduces the workload of the ICAO through an auditing process that cuts duplication of inspections to multiple EASA Member States. The ICAO need inspect only 2 or 3 Member States to validate the other Member States in EASA.
- **Staff**	776 Total. 679 Temporary Agents, 82 Contract Agents, 15 Seconded National Experts.
- **Financial**	Grand Total of EUR 185,423,159. Operational budget of EUR 130,441,000[56]. EU grant of 36,370,000[57] (28% of the operational budget.)
- **Fees and charges for using services (if relevant/ available)**	All certification services are a flat fee but vary in accordance with the product type. A fixed wing aircraft over 150,000 kg for instance is EUR 1,785,000, while an aircraft up to 2,000kg is EUR 13,940. Pricing is detailed in the Commission Regulation (EU) No. 319/2014.
Potential future development	The Agency will likely reduce the overall competencies and workload of NAAs, while expanding in industry-developing areas such as biodiversity, sustainable flying and unmanned aerial vehicles (drones). The aspiration is to develop a global common level of safety based on or at least harmonised with, the European standard.
Additional notes or comments	The Private Sector is heavily reliant on the international recognition of EASA, and allows it to compete internationally.

Name of Agency	**European Chemicals Agency - ECHA**
Date created	2007
Legislation	REACH Regulation (EC) 1907/2006[58] (also includes CLP) – "cruising speed" Biocides Regulation (EU) 528/2012[59] (as of 1 September 2013) –"start-up" Prior Informed Consent Regulation 649/2012[60] as of March 2014 – "new task"
Rationale for existence	Previous to REACH chemicals legislation was implemented at national level. This was deemed to have led to a deficit in testing of chemicals for purposes of ascertaining

[56] Including titles 1, 2 and 3 of the 2015 1st Amending Budget, and not including a one-off EUR 1.5 million payment for a new building infrastructure.
[57] Includes a one-off payment of approximately EUR 1.5 million for a new building for EASA (another EUR 1.5 million payment was budgeted for in 2016).
[58] Regulation (EC) No 1907/2006 of the European Parliament and the Council concerning the "Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)", and Regulation on "Classification, Labelling and Packaging of substances and mixtures" (CLP 11 Regulation (EC) No 1272/2008 of the European Parliament and the Council).
[59] Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal 14 products – the "Biocidal Products Regulation"
[60] Prior Informed Consent (PIC) Regulation (Regulation (EU) No 649/2012 of the European Parliament and of the Council concerning the export and import of hazardous chemicals)

	health, environmental and safety impacts. With the REACH Regulation registration was to take place centrally in the EU and there would be only one registration per substance, and standardised testing procedures. The process would also identify potential substances of very high concern and those which would need authorisation or restrictions for their use. ECHA was established for the purposes of managing and, in some cases, carrying out the technical, scientific and administrative aspects of the REACH Regulation and to ensure consistency of implementation of the Regulation at EU level. It was also established to manage tasks related to the classification and labelling of chemical substances, and subsequently the Biocides and Prior Informed Consent Regulations.
Agency objectives	The purpose of the REACH and CLP Regulations is to ensure a high level of protection of human health and the environment as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation. REACH is also designed to promote the development of alternative methods for assessing the hazards of substances. REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. At the same time, where needed, the European Union can take additional regulatory risk management measures on the most hazardous substances. ECHA manages core processes to achieve this: registration, evaluation, authorisation and restriction of chemical substances; as well as CLP, BPR and PIC.
Set up pre-agency	Before ECHA came into existence chemical companies who wanted to have tier substances registered for use in specific markets would have to apply to those member state authorities if their chemicals were not on an already approved list.
Main services/ outputs (number & type of clients and their location)	Generate high quality information for safe chemical manufacture and use; use information intelligently to identify and address chemicals of concern; addressing scientific challenges by serving as a hub for building the scientific and regulatory capacity of member states, European institutions and other actors; embrace current and new legislative tasks efficiently and effectively (while adapting to upcoming resource constraints)
- **Public sector**	Register chemical substances and test the quality of registration dossiers Maintain database of chemical substances, their characteristics and uses Harmonises standards of testing, evaluation, supervision and enforcement Share substance data Provides support – training, co0ordination, helpdesk Deals with enquiries - interpretations
- **Private sector**	Register substances Carry out assessments for Authorisation/ Restrictions of use of substances Organise exchange of standards and harmonisation between individual Member States for testing and evaluation Provides guidance on interpretation of legislation Database for substances
- **NGOs**	Single forum for engagement – rather than28 separate fora Data on SVHCs, environment, health, safety
- **Society**	ECHA is an Institution to monitor implementation of the REACH (and other) Regulation to ensure benefits of the regulations as regards health, safety and environmental protection are reaped.
- **Wider**	Contacts, share knowledge with OECD fora, DGENV, DGENTR. DGTRADE
- **Staff**	See table 3.1 (2015) CA – 103/ TA – 467/ total = 570
- **Financial**	See table 3.1 (2015) Total - EUR 114.8, EU grant - EUR 6.9 - 65
- **Fees and charges for using services (if relevant/ available)**	- Registration - Authorisation - Other - http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2015.139.01.0001.01.ENG

	Fees vary in terms of tonnages used, firm size and whether joint or single submissions, and what is being asked, from EUR 33699 to EUR 61.
Potential future development	The largest source of revenue – registrations, will end after the registration of 2018. What will be the non EU sources of revenue after then?

Name of Agency	**European Insurance and Occupational Pensions Authority - EIOPA**
Date created	2010
Legislation	Regulation (EU) No 1094/2010 of the European Parliament and of the Council of 24 November 2010 establishing a European Supervisory Authority (European Insurance and Occupational Pensions Authority)
Rationale for existence	It is understood that at political level there was no alternative to the introduction of the system, including the establishment of EIOPA, and this can be illustrated with a recital from EIOPA's founding regulation (Recital 1): 'The financial crisis in 2007 and 2008 exposed important shortcomings in financial supervision, both in particular cases and in relation to the financial system as a whole. Nationally based supervisory models have lagged behind financial globalisation and the integrated and interconnected reality of European financial markets, in which many financial institutions operate across borders. The crisis exposed shortcomings in the areas of cooperation, coordination, consistent application of Union law and trust between national supervisors.'
Agency objectives	EU 1094/2010: The objective of the Authority shall be to protect the public interest by contributing to the short, medium and long-term stability and effectiveness of the financial system, for the Union economy, its citizens and businesses. The Authority shall contribute to: (a) Improving the functioning of the internal market, including in particular a sound, effective and consistent level of regulation and supervision, (b) Ensuring the integrity, transparency, efficiency and orderly functioning of financial markets, (c) Strengthening international supervisory coordination, (d) Preventing regulatory arbitrage and promoting equal conditions of competition, (e) Ensuring the taking of risks related to insurance, reinsurance and occupational pensions activities is appropriately regulated and supervised, and (f) Ensuring customer protection.
Set up pre-agency	
Main services/ outputs (number & type of clients and their location)	EIOPA operates in four different areas: regulation and supervision, financial stability and crisis prevention, consumer protection and external relations. In those areas, the authority produces publications (such as guidelines), financial stability reports, provides technical advice to the EC, training and exchange of experiences… EIOPA's outputs and services need to be understood as serving a broader level of beneficiaries than the EU institutions, and this is identified with the wider interests of the European Union as a whole, including national authorities, companies and consumers. Most of the outputs seem to be of direct relevance to national authorities, private sector companies and consumers.
- **Public sector**	EIOPA is governed by a board of supervisors composed of the relevant national supervisory authority of each member state.
- **Private sector**	It is considered that EIOPA's work also benefit private sector companies.
- **NGOs**	EIOPA has a strong focus on consumers. EIOPA also organises meetings with stakeholders representing consumers, individually and as groups.
- **Wider**	EIOPA has a broad conception of target groups, identified as the wider EU interests, and comprising the EU institutions, national authorities, companies and consumers.
Resources (2015)	

- **Staff**	The 2015 Annual Report presents the Establishment Plan for 2015. This shows a total of 90 Temporary Agents. In addition, there are 32 Contract Agents and 19 Seconded National Experts.
- **Financial**	EIOPA has a budget of EUR 21 762 500 for 2016. The budget over the past three years was relatively stable: 2015: EUR 20 143 447 and 2014: EUR 21 414 562.
- **Fees and charges for using services (if relevant/ available)**	The EIOPA budget does not comprise fees and charges from private sector organisations. The EIOPA budget is constituted of contributions from national supervisory authorities (60% or EUR 13.3 million in EIOPA's total budget for 2016) and from the European Union (40% or EUR 8.5 million).
Potential future development	EIOPA has engaged in first reflections on the possible future introduction of fees / charges, and several issues require further clarification, e.g. the practicalities of collecting fees (via the national level or directly from companies?); legal implications in terms of EIOPA's services; the need to maintain EIOPA's independence and have governance arrangements reflect the new budget structure

Name of Agency	**European Medicines Association - EMA**
Date created	1995
Legislation	The Community codes for veterinary and human medicines are set out in Directive 2001/82/EC and Directive 2001/83/EC respectively. They provide the legal framework for the authorisation, manufacture and distribution of medicines in the EU. The centralised authorisation procedure for human and veterinary medicines is based on Regulation (EC) No 726/2004, which established the European Medicines Agency (EMA). The main EU legal framework for pharmaceuticals is based on: • Directive 2001/82/EC, on the Community code relating to veterinary medicinal products, as amended. The amendments are incorporated into the consolidated text of Directive 2001/82/EC; • Directive 2001/83/EC on the Community code relating to medicinal products for human use, as amended. The amendments are incorporated into the consolidated text of Directive 2001/83/EC; • Regulation (EC) No 726/2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended. The amendments are incorporated into the consolidated text of Regulation (EC) No 726/2004.
Rationale for existence	Facilitate a single market for medicines.
Agency objectives	EMA is responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU. The mission of EMA is to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health.
Set up pre-agency	Prior to EMA's establishment in 1995, there was no single procedure enabling the pharmaceutical industry to market their medicines throughout Europe and no harmonisation of the evaluation processes. Pharmaceutical companies therefore applied independently in each Member State.
Main services/ outputs (number & type of clients and their location)	EMA is a coordinating body. The Agency's current responsibilities include:

	• Coordination of the scientific evaluation[61] of applications for European marketing authorisation for both human and veterinary medicines (centralised procedure); • Monitoring of the safety of medicines through its pharmacovigilance network; • Coordination of inspections; • Stimulation of innovation and research through scientific advice and other assistance, and publication of guidelines; • Cooperation activities with international partners; • Involvement in referral or arbitration procedures (non-centralised procedure).
- **Public sector**	National Competent Authorities in the Member States
- **Private sector**	Pharmaceuticals industry
- **Wider**	WHO, FDA
- **Staff**	587[62]
- **Financial**	EUR 304.1 million (turnover)
- **Fees and charges for using services (if relevant/ available)**	**Scientific services** • The fee payable for an opinion on medicinal products for compassionate use is EUR 139,600 **Extension of marketing authorisations** • EUR 62,700 for medicinal products for human use. • EUR 31,500 for medicinal products for veterinary use. • EUR 8,700 for immunological veterinary medicinal products. **Type II variations** • By derogation from the applicable full fee of EUR 83,700 for medicinal products for human use and of EUR 41,800 for medicinal products for veterinary use (except for immunological medicinal products for which the fee shall be EUR 7,000 for all categories of variations). • The fee of EUR 62,700 for medicinal products for human use and EUR 31,500 for medicinal products for veterinary use is applicable for all quality variations. • The fee of EUR 20,900 for medicinal products for human use and EUR 10,500 for medicinal products for veterinary use is applicable to each of the third and subsequent type II variation that is grouped in a single application. **Annual fee** • Full fee of EUR 100,000 for medicinal products for human use and of EUR 33,400 for medicinal products for veterinary use. • EUR 50,000 for medicinal products for human use. • EUR 16,500 or medicinal products for veterinary use. • EUR 24,900 for medicinal products for human use authorised pursuant to Articles10(1), 10(3) and 10c of Directive 2001/83/EC. • EUR 8,300 for medicinal products for veterinary use authorised pursuant to Articles 13(1), 13(3) and 13c of Directive 2001/82/EC. **Inspections** • EUR 20,900 for medicinal products for human use and for medicinal products for veterinary use. • EUR 10,500 shall be payable when a distinct inspection that has been formally notified is cancelled […].[63]
Potential future development	The location of EMA is a potential future issue. The agency is currently located in London, UK.

[61] Scientific evaluation for: Initial evaluation; Specific Post-Authorisation activities; Pharmacovigilance and maintenance activities; Scientific advice and protocol assistance; Referrals; Orphan designation; Herbal medicinal products; Specified medicinal areas; Emerging and new therapies; and Inspections.

[62] Excluding Contract Agents and MS officials (secondments)

[63] For complete list and explanation of fees, see Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Medicines Agency and other measures
Revised implementing rules to the Fee Regulation as of 1 April 2016

Name of Agency	**European Banking Authority – EBA**
Date created	2011 – one pf the agencies created with ESMA and EIOPA as the Joint Committee for co-operation between ESMA and EIOPA collectively known as the three European Supervisory Agencies.
Legislation	The key legislation the EBA is to contribute to is the creation of the Single European Rule Book for the Capital Requirements Regulation (CRR) and the Capital Requirements Directive (CRD IV) and the Bank Recovery and Resolution Directive (BRRD Authority
Rationale for existence	Subsequent to financial crisis – this is one of the three agencies created by the Delaroisiere report to help ensure future EU financial stability. The predecessor organisations did not have sufficient resources or authority.
Agency objectives	To contribute to the creation and ensure the consistent application of the regulatory banking framework across the EU with the Single Rulebook, an on-line tool that provides a comprehensive compendium of the level one text for the Capital Requirements Regulation (CRR) and the Capital Requirements Directive (CRD IV) and the Bank Recovery and Resolution Directive (BRRD Authority), the corresponding technical standards developed by the European Banking (EBA) and adopted by the European Commission (RTS and ITS), as well as the EBA Guidelines and related Q&As (implementation at level 2 and level 3 legislation) in the different member states. The Authority also plays an important role in promoting convergence of supervisory practices and is mandated to assess risks and vulnerabilities in the EU banking sector The Authority also plays an important role in promoting convergence of supervisory practices and is mandated to assess risks and vulnerabilities in the EU banking sector.
Set up pre-agency	Before the existence of the EBA its work was CEBS Committee of European Banking Supervisors
Main services/ outputs (number & type of clients and their location)	
- **Public sector**	Produces the Single Rule Book; investigates alleged incorrect or insufficient application of EU law by national authorities; takes decisions directed at individual competent authorities or financial institutions in emergency situations; mediates resolves disagreements between competent authorities in cross-border situations; develops the methodological framework for peer reviews and conduct them on a regular basis; collects data disclose by the National Authorities in the Supervisory Review and Evaluation Process - SREP [Directive 2013/36/EU]; provides a semi-annual update on risks and vulnerabilities in the EU banking sector through the EBA's Risk Assessment Reports. They describe the main developments and trends that affect the EU banking sector and provide the EBA's outlook on the main micro-prudential risks and vulnerabilities. Article 32 of the EBA's funding Regulation task the Authority with monitoring and assessing market developments and providing information to other EU institutions and bodies (European Parliament, Council, European Commission, ESRB) and the general public.
- **Private sector**	Private sector uses Single Rulebook as a key reference that provides a comprehensive compendium of the level one text for the Capital Requirements Regulation (CRR) and the Capital Requirements Directive (CRD IV) and the Bank Recovery and Resolution Directive (BRRD), the corresponding technical standards developed by the European Banking Authority (EBA) and adopted by the European Commission (RTS and ITS), as well as the EBA Guidelines and related Q&A Works through the banking stakeholder group with about 30 members, including organisations such as the EBF. Provides harmonised prudential rules Promotes functioning of cross-border supervisory colleges Publish a list of authorised credit institutions in the EU
- **NGOs**	Protect consumer interests, e.g. work with consumer groups – e.g. transparency.
- **Wider**	ESMA, EIOPA, ESR, ECB, ResCO, ESRB, EC, EP,
Resources (2015)	
- **Staff**	TA – 120 CA – 31

	SNE - 14
- **Financial**	EUR 33.4 million, of which EUR 13.4 from the EU. Mainly from Member States. None from firms.
- **Fees and charges**	There are no fees or charges raised by the agency.

Name of Agency	**European Securities and Markets Authority - ESMA**
Date created	2011
Legislation	REGULATION (EU) No 1095/2010 of 24 November 2010 establishing a European Supervisory Authority (European Securities and Markets Authority), amending Decision No 716/2009/EC and repealing Commission Decision 2009/77/EC (OJ L 331, 15.12.2010, p. 84)
Rationale for existence	Following the financial crisis in 2008/9, the agency was created along with EBA and EUIOPA to ensure the stable functioning of the EU financial markets.
Agency objectives	Enhance the protection of investors and promote stable and well-functioning financial markets in the EU.
Set up pre-agency	National financial supervisory authorities coordinated their activities in Committee of European Securities Regulators (CESR) on an intergovernmental basis.
Main services/ outputs (number & type of clients and their location)	- Promote supervisory convergence (for National Competent Authorities/NCAs) - Assess risks to investors, markets and financial stability (public good) - Complete a single rulebook for EU financial markets (for European institutions and NCAs) - Direct supervision of specific financial entities (including 44 Credit Rating Agencies registered in 14 countries, including 11 EU Member States)
- **Public sector**	NCAs (financial supervisory authorities), the European Commission
- **Private sector**	Credit rating agencies, trade repositories, investors and the financial sector more generally
- **NGOs**	n/a
- **Wider**	
Resources (2015)	
- **Staff**	Total no. of staff in 2016: 202 (scheduled to rise to 235 in 2019), out of which 137 are temporary agents, 44 contract agents, and 21 seconded national experts
- **Financial**	Total executed budget in 2015: EUR 36,740,150
- **Fees and charges**	Revenue from fees in 2015: EUR 9,752,297
Potential future development	ESMA keeps working on creating rules for the EU financial market. Current major projects are supporting the implementation of the Markets in Financial Instruments Directive (MiFID) and MiFID II.

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