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Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision

Final Report

European Commission
Directorate-General for Health and Food Safety

Brussels/Rotterdam,

15 April 2016

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ECORYS

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IFAU (Institute for Food Studies & Agro-Industrial Development) is a SME founded in Denmark in 1982. IFAU's core business lies within collecting, analysing and disseminating applicable knowledge about food, agribusiness, and non-food related agribusiness products in a European and global view. IFAU's main fields of work encompass market analysis, strategic analysis, evaluations and surveys based literature reviews, interviews and stakeholder involvement. IFAU applies a product, company, or industry perspective at local, national as well as international topics. IFAU has a large network to companies, researchers, NGOs and government authorities across the Danish and Nordic food industry.

Linge Agroconsultancy is a consulting company in the field of registration of biocides, plant protection products and their active substances. Since its foundation in 2003, Linge provides a full range of registration services from data gap analysis to complete dossier preparations. The company carries out assignments for both the government and trade and industry. Linge has an extensive network of direct contacts with governmental authorities, biocide and plant protection companies, contract laboratories, institutes and universities.

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1 Introduction

1.1 Context and objectives of the study

In agreement with article 80 of the Regulation 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products, the Commission Implementing Regulation on the fees payable to the European Chemicals Agency (ECHA) has been adopted on 18 June 2013 (Commission Implementing Regulation (EU) No 564/2013). These fees are related to (i) the approval of active substances (annex I of the implementing regulation), (ii) the Union authorisation of biocidal products (annex II) and (iii) other activities like for example the submission fee for mutual recognitions (Annex III).

The principle of the fee is that it should allow to cover the costs of the different activities carried out by ECHA in the context of BPR. It means they should be set to a level ensuring a full recovery of the costs of the services provided including the costs of assessing the application plus overhead expenses such as for example the development of supporting documentations, the costs related to IT systems, helpdesk or controls.

Two years after the entry into force of the regulation, DG SANTE has requested an independent study to assess the appropriateness and impact of the current fees payable to ECHA. The study has three main objectives (1) support the EC for the preparation of the 2017 budget of ECHA, (2) provide recommendations on possible update of Regulation 564/2013 and (3) support the preparation of the Communication to the Council and the EP on biocide activities at ECHA for the period 2017-2020.

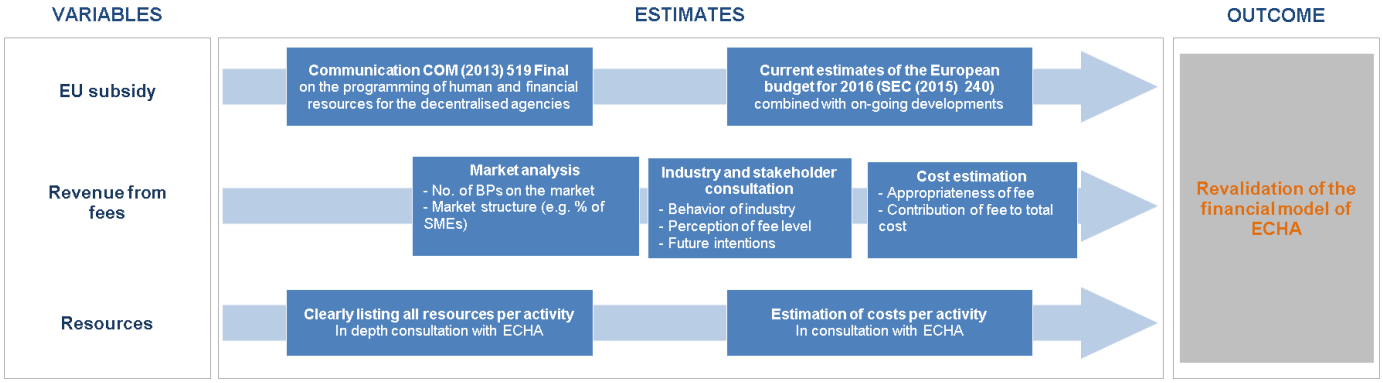
This draft final report provides the provisional results of the study that has been implemented between September 2015 and February 2016. The report will be updated in March 2016 following the comments that will be provided by the Steering Group.

1.2 Methodology

To achieve the objectives of the study, a new Excel spreadsheet summarising the ECHA's financing has been developed: the financial model made available to the consultant by DG SANTE has been completely redrafted and updated. It is designed to be used by both the European Commission and ECHA for current and future estimates.

This financial model include all relevant elements such as estimates of the number of applications, the number of required different categories of staff members, and the budget divided over the EU subsidy and revenue generated by fees. The overall approach proposed to revalidate the financial model of ECHA is presented in the Figure 1-1.

Figure 1-1 Overview the proposed approach for the revalidation of ECHA financial model



The estimates for ECHA's revenues, which are expected to come for a significant part from fees, are based on an analysis of the market and an industry consultation (both a survey and a consultation on the costs of bringing a Biocidal Product to the market). The estimates for submissions on Biocidal Product authorisations take into account the Review Programme as authorisations for Biocidal Products need to be submitted before the last applicable deadline for approval of the active substances they contain (two years after the Commission decision following the Biocidal Product Committees opinion). Expectations are that these deadlines induce a spike in submissions for both Union and National Authorisation. In order to make well-founded estimates, the average of Biocidal Products per active substance per product type currently on the market is also taken into account.

As there are many challenges in analysing the "biocides market", the estimates of the number of applications to Union Authorisations have been made for three "scenarios": one baseline scenario that takes into account the most recent trends, a conservative scenario that takes the hypothesis of a negative perception of the companies regarding the Union Authorisations process and a more optimistic scenario where no major issues are encountered and the industry has increasingly chosen to opt for Union Authorisation instead of National Authorisation plus Mutual Recognition.

Estimates for the costs are based on a cost accounting exercise following the principle of activity based costing. Firstly, to all activities ECHA undertakes, all the different related costs (i.e. the number and type of staff, the number of working days spent and other costs) are estimated. Secondly, for each activity related to either a dossier, a request or an opinion, an estimate of costs per unit is calculated. For more general or horizontal activities (i.e. the website, the helpdesk, communication activities, etc.) estimates are made on yearly basis. All calculations for staff start with estimates of working days spent per dossier/request/opinion and then calculated to Full Time Equivalent on yearly basis. The advantage of making FTE per dossier/request/opinion is that it clearly draws the link between the number of staff and the workload for a certain year and for a certain type of activity. This approach made it possible to allocate the costs related to each application to the year corresponding to the actual workload for ECHA staff (year N, N+1 and N+2).

The recommendations builds on the findings of three main simulations representing three main policy options. The first simulation considers a "status quo" situation with no change in the current Commission Implementing Regulation No 564/2013. The second simulation considers a change in the fee level and the third simulation a change in the payment conditions (payment of the fee in several instalments).

1.3 Structure of the report

The structure of the report is as follows:

- Chapter 2 provides a review of ECHA activities related to biocides. It covers fee-related activities and activities without fees related to active substance approval, biocidal products authorisations and other activities;
- Chapter 3 provides estimates of the costs for ECHA. The main assumptions used for the estimates are presented in section 3.1. The costs covered by fees are presented in section 3.2. These costs have been estimated by the consultants and revised by ECHA. The horizontal costs presented in section 3.3 have been provided by ECHA. In section 3.4 ECHA's costs and fees are compared;
- Chapter 4 include estimates for the number of applications to Union Authorisations. A review of the key drivers for ECHA's revenue building on the findings from a survey and market analysis is presented in section 4.1. The hypothesis retained for the estimates as well as the results for each year are presented in section 4.2;
- Chapter 5 presents the results of the simulations in three sections: 5.1 for the policy option A, "status quo", 5.2 for the Policy Option B "Change in the fee level" and 5.3 for the Policy Option C "Payment in instalments".
- The conclusions are presented in chapter 6.

The report is accompanied by an annex providing the results of the survey implemented in November 2015 (Annex 1), the details of the estimates of the number of application to Union Authorisation (Annex 2) and an overview of the current ECHA fees and the costs they intend to cover (Annex 3).The Excel files used for the simulations have also been provided to ECHA and to DG SANTE.

2 ECHA activities related to biocides

This chapter provides a detailed description of ECHA activities related to biocides. Information on the legal basis as well as an overview of the activities is provided in section 2.1. The activities related to active substance approval are presented in the section 2.2, the activities related to biocidal product authorisation in section 2.3 and other activities in section 2.4. The description is based on a detailed analysis of the legislation and on a consultation with ECHA.

2.1 Overview

The Biocidal Products Regulation (BPR, Regulation (EU) 528/2012) concerns the placing on the market and use of Biocidal Products, which are used to protect humans, animals, materials or articles against harmful organisms like pests or bacteria, by the action of the active substances contained in the Biocidal Product. This regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment. It repeals the Biocidal Products Directive (BPD, Directive 98/8/EC).

The BPR aims to harmonise the market at Union level; simplify the approval of active substances and authorisation of Biocidal Products and introduce timelines for Member State evaluations, opinion-forming and decision-making. It also promotes the reduction of animal testing by introducing mandatory data sharing obligations and encouraging the use of alternative testing methods.

As in the previous directive, the approval of active substances takes place at Union level (dossiers are submitted to ECHA which processes the application) and evaluated by a Member State (the evaluating competent authority) and the subsequent authorisation of the biocidal products and biocidal product families at Member State level. This authorisation can be extended to other Member States by mutual recognition. However, the new regulation also provides applicants with the possibility of a new type of authorisation at Union level (Union authorisation).

In agreement with article 80 of the Regulation 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products, the Commission implementing regulation No 564/2013 on the fees payable to the European Chemicals Agency (ECHA) has been adopted on 18 June 2013. These fees are expected to contribute to the coverage of the costs of the Agency for the work related to (i) the approval of active substances (Annex I of the implementing regulation), (ii) the Union authorisation of biocidal products (Annex II) and (iii) other activities like for example the submission fee for mutual recognitions (Annex III).

The principle of the fee is that it should, together with other sources of the Agency's revenue[1], allow; the coverage of costs related to the different activities carried out by ECHA in the context of BPR. It means they should be set to a level ensuring a full recovery of the costs of the services provided. The services of ECHA include activities for which fees are charged as well as activities without fees.

[1] See also recital 2 of Commission Implementing Regulation (EU) No. 564/2013 on the fees and charges payable to ECHA which states: "The structure and amount of the fees should take account of the work required by Regulation (EU) No 528/2012 to be carried out by the Agency. Fees should be set at such a level as to ensure that the revenue derived from them, when combined with other sources of the Agency's revenue, is sufficient to cover the cost of the services delivered."

Activities related to active substance approval and biocidal product authorisations are fee-based. However, a significant part of the activities related to active substances are inherited from the past (Review Programme and applications for new active substances made under the BPD) and are not source of fees for ECHA while representing a major part of its workload. In addition, activities such as maintenance of the ECHA BPR website, specification of formats and software packages for the submission of information to the Agency and assistance of the Commission or Member States are not covered by fees. All activities are presented in the table below, grouped according to funding-base.

Fees should be paid by the applicant after receipt of an invoice from ECHA. Exceptions are fees for appeals, which must be paid at the time of the submission of the appeal (Art. 8, CIR (EU) No 564-2013). A deadline for payment shall be considered to have been observed only if the full amount of the fee has been paid in due time, (Art. 11(1), CIR (EU) No 564-2013) meaning that paying in instalments is not possible.

Table 2-1 **Overview of ECHA activities**

Fee-related activities ECHA
Annex I
Approval of new active substances
Approval of existing active substances (the 'review programme'); Article 15, Reg. (EU) No 1062/2014
Notification of existing active substances (the 'review programme'); Article 17.4, Reg. (EU) No 1062/2014
Notification of existing active substances (the 'review programme'); Article 3(b), Reg. (EU) No 1451/2007
Renewal of active substance approvals
Inclusion in Annex I of an active substance; Article 28
Inclusion in Annex I of an existing active substance (the 'review programme'); Article 4, Reg. (EU) No 1062/2014
Annex II
Granting of Union Authorisation, single product or biocidal product family; Article 43(2)
Notification to ECHA of an additional product within a biocidal product family; Article 17(6)
Union authorisation of a same biocidal product; Article 17(7)
Major change of an authorised product or product family; Article 50(2)
Minor change of an authorised product or product family; Article 50(2)
Administrative change of an authorised product or product family; Article 50(2)
Recommendation on the classification of a change of an authorised product or product family; Article 50(2)
Renewal of Union authorisation, single product or biocidal product family; Article 45(3)
Annex III
Technical equivalence; Article 54(3)
Mutual Recognition Submission fee; Article 80(1)(a)
Annual fee for biocidal products authorised by the Union; Article 80(1)(a)
Appeal; Article 77(1)
Submission for inclusion in the list of relevant persons; Article 95
Requests under Article 66(4) submitted to ECHA

ECHA activities without fees
Management of the Review Programme
Overall management of the Review Programme
Approval of active substances submitted under the BPD (new active substances and existing active substances in the Review Programme)
Management of Article 95 list
Article 95 list management
Conducting checks and drafting opinions
Chemical similarity check (covered by a charge)
SME status check
Assistance to the Commission or Member States on Mutual Recognition Disagreements by drafting opinions
Other opinions at the request of the Commission or of Member States' competent authorities, any other questions that arise from the operation of this Regulation relating to technical guidance or risks to human health, animal health or the environment.
At the request of the Commission, providing technical and scientific support to improve cooperation between the Union competent authorities, international organisations and third countries on scientific and technical issues relating to biocidal products.
Support to data sharing (inquiries, data sharing disputes and permission to refer)
Organisation of meetings, Committees and working groups
Organisation of Biocidal Product Committee and its Working Groups
Organisation and Secretariat of the Coordination Group
Communication, Helpdesk
Communication activities (e.g. development of information webpages and practical guide, press relations, participation to conferences, etc.)
ECHA BPR Helpdesk
Submission management
Management of submissions (including submissions to Member States) and support to applicants
Transfer of submissions to Member States and related support to Member States
Maintenance of ECHA BPR website, including
Establishment and maintenance of database(s) with information on active substances and biocidal products;
Notification of decisions taken by ECHA;
Specification of formats and software packages for the submission of information to ECHA, including:
Establishment and maintenance of R4BP3 (Register for Biocidal Products) and the related SPC editor; Maintenance of IUCLID software package.
Providing technical and scientific guidance and tools for the application of this Regulation by the Commission and Member States' competent authorities and providing support to national helpdesks
Support of national helpdesks (HelpNet);
Development of BPR guidance documents.
Development of specific IT tools for scientific purposes
Providing support to Member States with regard to:
IT systems use and IT security
Managing IT systems database corrections
Enforcement authorities;
Avoiding the parallel assessment of applications relating to the same or similar biocidal products referred to in Article 29(4).

In the next pages, the general timeline and activities for all of ECHA's responsibilities under the BPR are explained. The descriptions are followed by a summary table indicating to which headings it refers in the Chapter 4 (on the costs of the Agency) and in the financial model. Every heading has received a code in order to maintain a structured overview.

2.2 Activities related to active substance approval

Approval and renewal of approval of active substances

The applicant should prepare a dossier for the active substance and its application in at least one representative biocidal product. The requirements for the active substance and for the biocidal product are set out in Annex II and Annex III of Regulation (EU) No 528/2012, respectively. The dossier should be prepared in IUCLID 5 format and submitted through R4BP 3.

After the validation check has been performed by ECHA, the evaluating competent authority (eCA) carries out a completeness check and an evaluation within one year. ECHA follows up the evaluation with regular exchanges with the eCA which may lead to specific actions including preliminary discussions in BPC working groups. During the evaluation process the applicant may be requested to submit additional information within 180 days after the request. The result of the evaluation is forwarded to ECHA's Biocidal Products Committee. If the active substance is found to be a potential candidate for substitution or exclusion a public consultation should be organised by ECHA. The Biocidal Products Committee prepares with the support of its working groups an opinion within 270 days; ECHA facilitates the Biocidal Products Committee's work by providing administrative, technical and scientific support to the evaluating competent authority, the BPC and its working groups.

The opinion serves as a basis for the decision-making by the European Commission and the Member States. The approval of an active substance is granted for a defined number of years, not exceeding ten years.

At least 550 days before the expiry of the approval the applicant submits an application for renewal of the active substance approval through R4BP 3. After the validation check has been performed by ECHA, the evaluating competent authority (eCA) determines whether a full evaluation of the application is necessary. In case no full evaluation is necessary, a recommendation on the renewal of the active substance is forwarded to ECHA's Biocidal Products Committee, which prepares with the support of its working groups an opinion within 90 days. In case a full evaluation is necessary, an assessment report and conclusions of its evaluation are forwarded to ECHA's Biocidal Products Committee, which prepares with the support of its working groups an opinion within 270 days. ECHA facilitates the Biocidal Products Committee's work by providing administrative, technical and scientific support to the evaluating competent authority, the BPC and its working groups.

The opinion serves as a basis for the decision-making by the European Commission and the Member States. The renewal of approval of an active substance is granted for a defined number of years, not exceeding ten years

Table 2-2. Codes and activity headings related to active substances

Code	Activity heading	Covered by fee
AS01	Approval of an active substance for the first PT	Yes
AS02	Approval of an active substance when there is an additional PT	Yes
AS03	Approval of an active substance per extra PT if candidate for substitution	Yes
AS04	Approval for the amendment of an approval, other than the addition of a PT	Yes
AS05	Renewal of an approval of an active substance for the first PT	Yes
AS06	Renewal of an approval of an active substance per additional PT	Yes
AS07	Renewal of an approval of an active substance for the first PT when a full evaluation is found necessary	Yes
AS08	Renewal of an approval of an active substance per additional PT when a full evaluation is found necessary	Yes
AS09	Renewal of an approval of an active substance for the first PT if candidate for substitution	Yes

Code	Activity heading	Covered by fee
AS10	Submissions for the first inclusion in Annex I of an active substance	Yes
AS11	Submissions for the amendment of an inclusion of an active substance in Annex I	

Technical equivalence assessment

Companies need to submit an application through R4BP 3 to ECHA in order to allow it to assess technical equivalence of the active substance from an alternative source. Once ECHA has made the assessment, the applicant is given the opportunity to comment the outcome of the assessment. These comments are considered by ECHA and may lead to a revision of the assessment. Overall, ECHA shall take the final decision within 90 days from the date in which the application fee has been paid, excluding, when relevant, periods needed by the applicant to provide additional data requested by ECHA.

Table 2-3. Codes and activity headings related to technical equivalence

Code	Activity heading	Covered by fee
TE01	Technical equivalence when difference between the AS sources is limited to a change in manufacturing location, and application is based solely on analytical data	yes
TE02	Technical equivalence when difference between the AS sources goes beyond a change in the manufacturing location, and application is based solely on analytical data	yes
TE03	Technical equivalence when the previous conditions are not met	yes

Chemical similarity check

A chemical similarity check is an assessment similar to the technical equivalence assessment described in Article 54 of Regulation (EU) No 528/2012. However it is performed solely on the substance identity and chemical composition with the aim to establish similarity as regards the chemical composition of a second substance. Contrary to technical equivalence, it is not limited to approved active substances. This service is not defined in the legislation and has been proposed by ECHA in response to comments made by Member States and Commission on the limitations of the scope of technical equivalence. This service is not subject to the payment of a fee but of a charge which has been agreed by the Commission and ECHA's Management Board (ECHA Management Board Decision 31/2013: Decision of the Management Board on the service charge for Chemical similarity check performed for biocidal active substances).

To assess the chemical similarity, companies need to submit an application through R4BP 3 to ECHA. ECHA carries out the assessment and informs applicant about whether or not the active substance is found to be chemically similar. No fixed time frame is given.

Table 2-4. Code and activity heading related to chemical similarity check

Code	Activity heading	Covered by fee
CS01	Check for chemical similarity: Comparison of one source with an active substance (existing or new) under evaluation under BPD or BPR. Temporary reference source exists.	Not a fee but a charge
CS02	Check for chemical similarity: Comparison of one source with an active substance (existing or new) under evaluation under BPD or BPR. Temporary reference source does not exist and only one participant has submitted a dossier under the Review Programme for existing active substances or under new active substance approval (Article 7 of the BPR or Article 11 of BPD)	Not a fee but a charge

Code	Activity heading	Covered by fee
CS03	Check for chemical similarity: Comparison of one source with an active substance (existing or new) under evaluation under BPD or BPR. Temporary reference source does not exist and more than one participant has submitted a dossier under the Review Programme for existing active substances or under new active substance approval (Article 7 of the BPR or under Article 11 of BPD)	Not a fee but a charge
CS04	Check for chemical similarity: additional dossier	Not a fee but a charge
CS05	Check for chemical similarity: Comparison of two or more sources of an active substance which is not yet under evaluation under BPD or BPR. Two datasets submitted for comparison.	Not a fee but a charge
CS06	Check for chemical similarity: Comparison of two or more sources of an active substance which is not yet under evaluation under BPD or BPR. Three or more datasets submitted for comparison.	Not a fee but a charge
CS07	Check for chemical similarity: additional dataset	Not a fee but a charge

2.3 Activities related to biocidal product Authorisations

Union Authorisation, amendments and renewal

Before submission of an application for Union Authorisation the applicant can request a pre-submission consultation. These consultations aim to give future applicants for authorisation the opportunity to receive feedback on the eligibility for Union Authorisation of their potential application. Pre-submission consultations should be started at the latest six months before the planned submission of the application for authorisation. One such session is envisaged per application.
No fee is charged for a pre-submission consultation.

The applicant should prepare a dossier for the biocidal product in the relevant product type. The requirements for the biocidal product are set out in Annex III of Regulation (EU) No 528/2012 (amended by Commission Delegated Regulation (EU) No 837/2013). The dossier should be prepared in IUCLID 5 and SPC format and submitted to ECHA through R4BP 3. Applications for Union Authorisation are evaluated by a designated Member State (evaluating competent authority eCA). ECHA is responsible for ensuring that the information in the dossiers is in a correct format and makes sure that the submission process proceeds within the set timelines. The evaluating competent authority is responsible for carrying out the validation of the application dossiers and for the evaluation of the dossier submitted by the applicant. ECHA follows up the evaluation with regular exchanges with the eCA which may lead to specific actions including preliminary discussions in BPC working groups. ECHA facilitates the Biocidal Products Committee's work by providing administrative, technical and scientific support to the evaluating competent authority, the BPC and its working groups. The BPC with the support of its working groups delivers an opinion on the authorisation of the biocidal product. ECHA is also responsible for coordinating the checking by the Member States of the translations of the agreed summary of biocidal product characteristics in all official languages. The European Commission, assisted by the Standing Committee on Biocidal Products, takes the opinion issued by the BPC into consideration and decides whether to grant a Union authorisation or not.

Amendment of a Union Authorisation includes administrative changes, minor and major changes. The applicant can apply for changes at any time. If necessary, ECHA can be requested to classify a considered change, either for Union Authorisation or National Authorisation. For minor changes to UA, ECHA has to draft an opinion. For major changes, ECHA has a coordinating role for the peer review process and drafts an opinion..

Table 2-5. Codes and activity headings related to Union Authorisation

Code	Activity heading	Covered by fee
UA01	Pre-submission consultation for Union Authorisation	No
UA02	Union Authorisation of a single product, not identical with (one of) the representative product(s) assessed for the purpose of substance approval	Yes
UA03	Union Authorisation of a single product, identical with (one of) the representative product(s) assessed for the purpose of the substance approval	Yes
UA04	Union Authorisation of a single product, when a comparative assessment is required	Yes
UA05	Union Authorisation of a single product when the requested information is provisional	Yes
UA06	Union Authorisation for a product family	Yes
UA07	Union Authorisation for a product family when comparative assessment is required	Yes
UA08	Union Authorisation for a product family when the requested Authorisation is provisional	Yes
UA09	Union Authorisation for an additional product within a product family	Yes
UA10	Union Authorisation for a same biocidal product	Yes
UA11	Recommendation on a classification of change per product	Yes
UA11	Recommendation on a classification of change per family	Yes
UA12	Major change of an authorised product	Yes
UA13	Minor change of an authorised product	Yes
UA14	Administrative change of an authorised product	Yes
UA15	Renewal of UA for a single product	Yes
UA16	Renewal of UA for a single product if a full evaluation is found necessary	Yes
UA17	Renewal of UA for a single product when comparative assessment is required	Yes
UA18	Renewal of UA for a product family	Yes
UA19	Renewal of UA for a product family when a full evaluation of is found necessary	Yes
UA20	Renewal of UA for a product family when comparative assessment is required	Yes

Mutual recognition applications and renewals

The applicant should prepare a dossier for the biocidal product in the relevant product type. The requirements for the biocidal product are set out in Annex III of Regulation (EU) No 528/2012 (amended by Commission Delegated Regulation (EU) No 837/2013). The dossier should be prepared in IUCLID 5 format and submitted through R4BP 3.

ECHA performs the tasks relating to the acceptance of the application and the ECHA fee invoicing. No fees are charged by ECHA for renewals of product authorisations by mutual recognition.

ECHA also provides the secretariat of the coordination group which primary mission is to address mutual recognition disputes between MSCAs. If the coordination group fails to reach an agreement the Commission may ask ECHA for an opinion on scientific or technical questions raised by Member States T= 210 -575 d). The BPC prepares within 120 days the opinion of ECHA on scientific and technical matters concerning mutual recognition.

Table 2-6. Codes and activity headings related to mutual recognition

Code	Activity heading	Covered by fee
MR01	Mutual Recognition submission	Yes
MR02	Mutual Recognition disagreements – opinions	No
MR03	Mutual recognition renewal	No

Alternative supplier application (Article 95)

From 1 September 2015, a biocidal product consisting of, containing, or generating a relevant substance, cannot be made available on the EU market if the substance supplier or product supplier is not included in the list for the product type to which the product belongs. Companies that have not already submitted their own dossier on an active substance under the Biocidal Products Directive (BPD) or the BPR can either submit a dossier, a letter of access, or if all data protection periods have expired, a reference to an existing dossier to ECHA. This information must comply with the data requirements for active substances of the BPR or the BPD.

Furthermore, ECHA is responsible for the overall management of the article 95 list which implies the coordination with Member States' Competent Authorities.

Under the article 95 applications the tasks of ECHA cover administrative work (checking any conflicts of interest, allocation, monitoring and sending of draft and final decisions, recording of related documentation, etc.) and assessments of the compliance of the submitted data. ECHA drafts the final decision and processes all of the received comments and/or the additional data provided for the final decision. Additionally, ECHA also advises industry by organising e.g. webinars. The workload however, is expected to be reduced after the end of 2015.

Table 2-7. Codes and activity headings related to active substances and the Review Programme

Code	Activity heading	Covered by fee
AS12	Inclusion in the list of relevant persons under art. 95 with a letter of access to a dossier already found complete by the Agency or the eCA	Yes
AS13	Inclusion in the list of relevant persons under art. 95 with a letter of access to part of a dossier already found complete by the Agency or the eCA, together with complementary data	Yes
AS14	Inclusion in the list of relevant persons under art. 95 if a new dossier is submitted	Yes
RP01	Overall management of the Review Programme	No
RP02	Dossier management of the Review Programme	No
RP03	Art. 95 list management	No

2.4 Other activities

Appeal

The Biocidal Products Regulation foresees the possibility to appeal certain decisions taken by the European Chemicals Agency before the ECHA Board of Appeal. An appeal will be considered to be received only once the applicable fee has been received. The appeal, together with the statements of the grounds thereof, shall be filed in writing to ECHA within three months of the notification of the decision appealed against. If, after consultation with the Chairman of the Board of Appeal, the Executive Director considers the appeal to be admissible and well-founded he may rectify the decision within 30 days of the appeal being filed. Otherwise the Chairman of the Board of Appeal shall examine whether the appeal is admissible within 30 days of the appeal being filed. ECHA has the opportunity to lodge the defence within two months after being notified of the notice of appeal.

Table 2-8. Code and activity heading related to appeal

Code	Activity heading	Covered by fee
AP01	Appeal (work of the Board of Appeal)	Yes
AP02	Defence and support for the defence against the appeal	No

Request for confidentiality

ECHA and the competent authorities shall refuse access to information where disclosure would undermine the protection of the commercial interests or the privacy or safety of the persons concerned, such as product composition, tonnage made available on the market, links between manufacturers and distributors and personal data involving testing on vertebrates.

Other information like name and address of authorisation holder, manufacturer, active substance content, physical chemical data and data on risks, hazards and safety will be made public.

Any person submitting information related to an active substance or a biocidal product to ECHA or a competent authority for the purposes of this Regulation may request that this information is not made publicly available, including a justification as to why the disclosure of the information could be harmful for that person's commercial interests or those of any other party concerned. This request may be addressed to either the relevant national competent authority or ECHA. In addition, ECHA provides support and assistance to Member States with regard to confidentiality claims to be assessed by them (requests under Article 66(4) BPR).

Table 2-9. Code and activity heading related to requests for confidentiality

Code	Activity heading	Covered by fee
CO01	Request for confidentiality	Yes
CO02	Support for request for confidentiality handled by Member State	No

SME Status Check

Any company can request at any time an application for verification of its SME status, ECHA performs the SME verification and concludes on the status of the company. During the SME verification procedure, ECHA assesses all documentation requested, with possible follow-up requests. When the applicant found to be a SME will apply within the two years following the date of ECHA decision for Union authorisation or approval of a new active substance, ECHA will invoice the applicable reduced fee.

Table 2-10. Code and activity heading related to the SME status check

Code	Activity heading	Covered by fee
SC01	SME status check/verification	No

Support in data-sharing

Written requests need to be made to the Agency in order to determine whether animal or vertebrate testing have already been submitted to the Agency or the Member State Competent Authorities. ECHA should then perform a verification test to see if such information has already been submitted. The Agency will transmit the name and contact details of the data submitter and the data owner to the applicant.

When the data owner and the applicant for data – sharing are not able to come to an agreement with regard to compensation in a fair, transparent and non-discriminatory manner, the applicant can request a data sharing dispute procedure with the Agency at the earliest one month after the information request had been submitted. Within 60 days, ECHA will make an assessment of parties' efforts made to reach an agreement and in case of the decision favourable to the applicant; ECHA will issue a decision granting the permission to refer to the information of data owner. In case of decision not favourable to the applicant ECHA will issue a decision requesting both parties to continue their negotiations based on ECHA recommendations/observations in order to reach a voluntary agreement, specifying that applicant may re-submit its case, should the subsequent negotiations fail again.

Table 2-11. Codes and activity headings related to data-sharing

Code	Activity heading	Covered by fee
DS01	Processing data-sharing enquiries	No
DS02	Assistance in data-sharing disputes	No

Organisation of meetings, Committees and Working Groups

ECHA provides all the logistical, administrative and scientific support to all meetings, Committee and Working Groups organised. ECHA chairs the BPC and its working groups and has a scientific secretariat supporting the discussions. Furthermore, ECHA provides all necessary administrative support with regard to members, the dissemination of files, management of supporting documentation and conflicts of interest and the management of the CIRCA BC access. ECHA also organises and supports the coordination group which primary mission is to address mutual recognition disputes between MSCAs.

For its first two years of operation (2014 and 2015), ECHA has prepared 35 and 50 opinions respectively. In 2016, 60-65 opinions are foreseen and the number of opinions is foreseen to grow in the future, especially with the addition of opinions for Union authorisation.

Table 2-12. Codes and activity headings related to the organisation of meetings, Committees and Working Groups

Code	Activity heading	Covered by fee
ME01	Organising and supporting Committees and Working Groups, including preparation of opinions.	No
ME02	Organising and supporting the Coordination Group	No

Communication, Helpdesk and Guidance

Activities under communication cover the updating of the website which is the European hub for institutional information on biocides, organising events, writing and distributing e-news, press releases, leaflets or other documents, and managing press enquiries.

The ECHA BPR helpdesk processes on average more than 100 requests (each usually corresponding to more than one question) each month. Furthermore, ECHA is responsible for the management of HelpNet (Network of national BPR, CLP and REACH helpdesks).

ECHA offers guidance by supervising, drafting and organising external consultations (partner expert group, Commission, Member States, stakeholders) and is responsible for revising, editing and publishing the final guidance publications.

Table 2-13. Codes and activities headings related to communication, Helpdesk and guidance

Code	Activity heading	Covered by fee
HD01	Communication activities	No
HD02	Helpdesk and HelpNet	No
HD03	Guidance	No

Dissemination

ECHA establishes and maintains databases with information on:

- active substances and biocidal products;
- notification of decisions taken by ECHA (except for decisions related to Article 95 and technical equivalence).

Table 2-14. Code and activity heading related to website maintenance

Code	Activity heading	Covered by fee
DI01	Dissemination	No

Specification of formats and software packages for the submission of information to the Agency

ECHA establishes and maintains the software packages R4BP 3 (Register for Biocidal Products), SPC editor and IUCLID. These software packages are required for the submission of information to ECHA and the Member States' competent authorities.

Table 2-15. Code and activity heading related to IT

Code	Activity heading	Covered by fee
IT01	Formats and software packages	No

Assistance to the Commission or Member States

ECHA provides assistance to the Commission or Member States:

- at the request of the Commission or of Member States' competent authorities, on any question that arise from the operation of the BPR relating to technical guidance or risks to human health, animal health or the environment (BPC);
- at the request of the Commission, providing technical and scientific support to improve cooperation between the Union competent authorities, international organisations and third countries on scientific and technical issues relating to biocidal products (Secretariat);
- with regard to control and enforcement activities in Member States (Secretariat);
- by support of national helpdesks (Secretariat).

Table 2-16. Code and activity heading related to drafting other opinions

Code	Activity heading	Covered by fee
OP01	Drafting other opinions	No

Annual fees

ECHA charges an annual fee per Union Authorisation of a biocidal product or product family. ECHA activities include invoicing and financial reconciliation costs: (including when necessary support to applicant).

Table 2-17. Code and activity heading related to annual fees

Code	Activity heading	Covered by fee
UA21	Fee per Union authorisation of a biocidal product	Yes
UA22	Fee per Union authorisation of a biocidal product family	Yes

3 Analysis of costs for ECHA biocides-related activities

This chapter provides the results of the estimates on the costs for all ECHA activities related to the biocides. The assumption retained for the estimates are presented in section 4.1. Estimates of the costs covered by the fees are provided in section 4.2 and for horizontal activities in section 4.3. The costs covered by the fees have been estimated by the consultants and revised by ECHA. The horizontal costs have been provided by ECHA.

3.1 Introduction – assumption retained for the estimates

In order to estimate the costs for ECHA in conducting all of their responsibilities under the Biocides heading, an Activity-Based Costing method is used. On the one hand, the direct costs per activity (i.e. the ones identified in Chapter 2) per dossier/request/opinion are estimated. On the other hand, a number of cost drivers (FTE of staff needed, other costs, etc.) are identified per activity. They will used to allocate overhead costs to the different activities under ECHA's responsibilities: indirect costs are distributed more accurately to certain tasks in order to a more accurate picture of the costs per tasks.

In order to list all activities of ECHA and assign costs to each of them, estimations have made on the number of days staffs spend on each activity in every phase of the process. These estimates are taken from the staff model as provided by ECHA drafted in October 2015 and inputs for this study during December 2016. Estimates are formulated in FTE per dossier/request/opinion or FTE per year for horizontal activities (such as communication, the Helpdesk, etc.). In order to estimate the total cost per dossier/request/opinion for staff, the FTE is multiplied with the average yearly wage as calculated in the budget model for ECHA as provided by the European Commission. In order to have a useful tool for the future, the Excel financial model provides the option to adjust all of these parameters related to the costs.

The estimates made on the costs are based on the following assumptions:

- A workweek consists of 40 hours, so one working day is 8 hours;
- There are 220 working days available in a year;
- The annual costs for ECHA of a temporary agent (TA, both AD and AST) amount to € 128 874 and for a contract agent (CA) to € 86 596. The day rates are based upon these costs which include in particular salary, taxes, training costs, recruitment costs, contribution to the European systems of pension and medical expenses;
- The number of days needed for every activity is based upon estimations made by the consultants in December 2015 and validated by ECHA in January 2016;
- The costs of the horizontal activities have been provided by ECHA.
- Where application generate the organisation of the BPC, it should be noted that these direct costs are not included in the specific costs for the activities related to this application. Rather, the costs of organising the BPC are included as an horizontal cost.
- Overheads are not included in the costs for every activity.

3.2 Costs covered by fees

Costs related to activities under Annex I

Table 3-1 Approval of active substance

AS01	Approval of active substance
Legal basis	Reg (EU) 528/2012, Art 7-8; Reg (EU) 528/2012, Art 75(1)a; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 75(1)d; Reg (EU) 528/2012, Art 10(2)
Short description	**Activities for the first product type for which that active substance is approved**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA examines whether the active substance fulfils the criteria of candidates for substitution. ECHA accepts submission after payment of fees (T= 30 d) and informs applicant and the evaluating competent authority (eCA) accordingly. ECHA is informed about validation of application by the evaluating competent authority (eCA) (T= 60-150 d). The evaluating competent authority (eCA) sends assessment report and conclusions of its evaluation to ECHA (T= 425-695 d, however the applicant can request a clock stop which should not exceed 180 d in total, unless it is justified by the nature of the data requested or by exceptional circumstances). ECHA coordinates and contributes to the commenting activities of the other MSCAs. When the draft assessment report indicates that the active substance is considered candidate for substitution or exclusion, ECHA organises a public consultation and report its outcomes The BPC working groups discuss the outstanding technical and scientific issues related to the draft assessment report in order to finalise it. Biocidal Products Committee (BPC) prepares the opinion of ECHA on the application and if active substance is considered candidate for substitution. ECHA submits to the Commission the opinion on the approval of the active substance (T= 695-965 d, yet in practice this might be different due to process flows with submission windows).
Costs related to the activities	**Activities of BPC start 395-665 d after the fee was received by ECHA, however activities in the Working Groups can start earlier** Invoicing and financial reconciliation costs: € 219,7 Labour AD desk officer at public consultation phase (5 days): € 2 929 Labour AD desk officer during peer review phase (25 days): € 14 645 Labour AST desk officer (4 days): € 2 343.2 Support by legal unit (1.125 days for normal cases and 2.5 days for in situ generated active substances – an average of 1.81 days is used): € 703 **Total costs per amendment: € 20 840**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, **N+1:** public consultation & peer review, **N+2:** peer review.

AS02	Approval of active substance
Legal basis	Reg (EU) 528/2012, Art 7-8; Reg (EU) 528/2012, Art 75(1)a; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 75(1)d
Short description	**Activities for the additional product type for which that active substance is approved**
Description of the activities performed by ECHA	See description of activities for the first product type for which that active substance is approved. In case of one submission containing more than one PT, activities ECHA are reduced to preparation of opinion on the application.
Costs related to the activities	**Activities of BPC start 395-665 d after the fee was received by ECHA, however activities in the Working Groups can start earlier.** Labour AD desk officer support of peer review phase (25 days)[2]: € 14 645 Labour AST desk officer in peer review phase (4 days): € 2 343.2 Support by legal unit (1.125 days for normal cases and 2.5 days for in situ generated active substances – an average of 1.81 days is used): € 703 **Total costs per dossier: € 17 691**
Years that costs will be allocated	**N+1:** peer review, **N+2:** peer review.

AS03	Approval of active substance
Legal basis	Reg (EU) 528/2012, Art 7-8; Reg (EU) 528/2012, Art 75(1)a; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 75(1)d; Reg (EU) 528/2012, Art 10
Short description	**Additional activities per product type (for both the first product- type and any additional product type) if the active substance is a candidate for substitution in accordance with Article 10 of Regulation (EU) No 528/2012**
Description of the activities performed by ECHA	See description of activities for the first product type for which that active substance is approved.
Costs related to the activities	**Activities of BPC are finalised up to 180 days before the invoice for the additional fee is sent by ECHA (the decision on substitution candidacy is made at final EC decision).** Labour: ECHA organises the public consultation and report on its outcomes. Labour AD desk officer support of peer review phase (5 days)[3]: € 2 929 Labour AST desk officer in peer review phase (2 days): € 1172 **Total costs per additional product type: € 4 101**
Years that costs will be allocated	**N+1:** public consultation & peer review, **N+2:** peer review.

[2] (and when necessary public consultation) + preparation of draft BPC opinion + supervision of revision of assessment report and BPC opinion + preparation and follow-up of WG and BPC discussions (preparation of discussion tables, action points, minutes, ad-hoc follow ups, etc.), stages 4-5 (25 days)

[3] (and when necessary public consultation) + preparation of draft BPC opinion + supervision of revision of assessment report and BPC opinion + preparation and follow-up of WG and BPC discussions (preparation of discussion tables, action points, minutes, ad-hoc follow ups, etc.), stages 4-5 (25 days)

AS04	Approval of active substance
Legal basis	Reg (EU) 528/2012, Art 7-8; Reg (EU) 528/2012, Art 75(1)a; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 75(1)d;
Short description	**Activities for the amendment of an approval, other than the addition of a product type.**
Description of the activities performed by ECHA	See description of activities for the first product type for which that active substance is approved.
Costs related to the activities	**Activities of BPC start 395-665 d after the fee was received by ECHA, however activities in the Working Groups can start earlier.** Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. Labour depends on kind of amendment. Labour AD desk officer at public consultation phase (5 days): € 2 929 Labour AD desk officer during peer review phase (25 days): € 14 645 Labour AST desk officer (4 days): € 2 343.2 Support by legal unit (1.125 days for normal cases and 2.5 days for in situ generated active substances – an average of 1.81 days is used): € 703 **Total costs per amendment: € 20 620**
Years that costs will be allocated	**N+1:** public consultation & peer review, **N+2:** peer review.

Table 3-2 Notification in accordance with Article 17 of Regulation (EC) No 1062/2014

AS08	Notification in accordance with Article 17 of Regulation (EC) No 1062/2014
Legal basis	Reg (EC) 1062/2014, Art 17;
Short description	**Activities per substance/product type combination.**
Description of the activities performed by ECHA	ECHA receives notification that applicant wishes to take over the role of a participant in the Review Programme or expressing interest in a AS/PT combination via R4BP and informs applicant of fees to be paid. (T= 0). ECHA starts the assessment of the notification after payment of fees (T= 30 d), assesses the compliance of the notification with the legal requirements and informs the applicant and the evaluating competent authority (eCA) of the conclusion of its assessment.
Costs related to the activities	The fee for the notification shall be deducted from the subsequent application in accordance with Article 7 of Regulation (EU) No 528/2012.
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, assessment of notification

Table 3-3 **Renewal of active substance approvals**

AS05	Renewal of active substance approvals
Legal basis	Reg (EU) 528/2012, Art 13-15; Reg (EU) 528/2012, Art 75(1)a; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 75(1)d;
Short description	**Activities for the first product type for which renewal of that active substance is sought**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA examines whether the active substance fulfils the criteria of candidates for substitution. ECHA accepts submission after payment of fees (T= 30 d) and informs applicant and the evaluating competent authority (eCA) accordingly. ECHA is informed by the evaluating competent authority (eCA) whether a full evaluation of the application is necessary (T= 120 d). In case no full evaluation is necessary, a recommendation on the renewal of the active substance is submitted to ECHA by the evaluating competent authority (eCA) (T=210 d). ECHA coordinates and contributes to the commenting activities of the other MSCAs. The BPC working groups discuss the outstanding technical and scientific issues related to the recommendation or the draft assessment report in order to finalise it. BPC prepares and ECHA submits its opinion on the renewal to the Commission (T= 300 d).
Costs related to the activities	**Activities of BPC start 180 d after the fee was received by ECHA, however activities in the Working Groups can start earlier.** Invoicing and financial reconciliation costs: € 146.5 Labour AD desk officer evaluation phase (5 days): € 2 929 Labour AD desk officer facilitating BPC work (10 day): € 5 858 Labour AST desk officer in peer review phase (4 days): € 2 343.2 Support by legal unit (0.75 days for normal cases and 1.5 days for in situ generated active substances – an average of 1.125 days is used): €469 **Total costs per dossier: € 11 745**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, facilitating BPC work **N+1:** evaluation, facilitating BPC work & peer review, **N+2:** peer review.

AS06	Renewal of active substance approvals
Legal basis	Reg (EU) 528/2012, Art 13-15; Reg (EU) 528/2012, Art 75(1)a; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 75(1)d;
Short description	**Additional activities per additional product type for which renewal of that active substance is sought**
Description of the activities performed by ECHA	See description of activities for the first product type for which renewal of that active substance is sought.
Costs related to the activities	Activities of BPC start 180 d after the fee was received by ECHA. Travel costs and accommodation of Members of the Biocidal Product Committee are paid by ECHA. Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. For product type-independent data the assessment report and conclusions will refer to evaluation of first product type. The evaluating competent authority (eCA) and BPC will only evaluate additional product type specific data. Therefore labour of Biocidal Products Committee will be reduced. Labour AD desk officer in evaluation phase (5 days): € 2 929 Labour AD desk officer facilitating BPC work in peer review phase (10 days)[4]: € 5 858 Labour AST desk officer in peer review phase (4 days): € 2 343.2 Support by legal unit (0.75 days for normal cases and 1.5 days for in situ generated active substances – an average of 1.125 days is used): € 469 **Total costs per dossier: € 11 599**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, facilitating BPC work **N+1:** evaluation, facilitating BPC work & peer review, **N+2:** peer review.

[4] by supporting eCA, BPC & working groups, evaluating eCA reports and comments MSCAs, writing down BPC opinion, stages 4-5 (10 days)

AS07	Renewal of active substance approvals
Legal basis	Reg (EU) 528/2012, Art 13-15; Reg (EU) 528/2012, Art 75(1)a; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 75(1)d;
Short description	**Additional activities for the first product type for which renewal of that active substance is sought in case a full evaluation is found necessary in accordance with Article 14(1) of Regulation (EU) No 528/2012**
Description of the activities performed by ECHA	ECHA is informed by the evaluating competent authority (eCA) that a full evaluation of the application is necessary (T= 120 d). ECHA accepts submission after payment of the additional fee invoiced for full evaluation (T= 30 d, generally but depends on the information given by the eCA) and informs applicant and the evaluating competent authority (eCA) accordingly. The evaluating competent authority (eCA) sends assessment report and conclusions of its evaluation to ECHA (T= 395 d). ECHA coordinates and contributes to the commenting activities of the other MSCAs. The BPC working groups discuss the outstanding technical and scientific issues related to the draft assessment report in order to finalise it. Biocidal Products Committee (BPC) prepares the opinion of ECHA on the application. ECHA submits to the Commission the opinion on the approval of the active substance (T= 565 d).
Costs related to the activities	**Activities of BPC start 365 d after the first fee was received by ECHA and 175 d after the additional fee was received** Description of Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. The evaluating competent authority (eCA) and BPC will evaluate new relevant data generated since previous approval and whether the conclusions of the previous assessment of the active substance remain valid. Labour AD desk officer in peer review phase (10 days additional): € 5 858 Support by legal unit (0.4 days): € 234 **Additional costs per dossier: € 6 092**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, **N+1:** evaluation & peer review, **N+2:** peer review.

AS08	Renewal of active substance approvals
Legal basis	Reg (EU) 528/2012, Art 13-15; Reg (EU) 528/2012, Art 75(1)a; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 75(1)d;
Short description	**Additional activities per additional product type in case a full evaluation is found necessary in accordance with Article 14(1) of Regulation (EU) No 528/2012**
Description of the activities performed by ECHA	See description of activities for the first product type for which renewal of that active substance is sought. In case of one submission containing more than one PT, activities ECHA are reduced to preparation of opinion on the application
Costs related to the activities	**Activities of BPC start 365 d after the first fee was received by ECHA and 175 d after the additional fee was received** Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. For product type-independent data the assessment report and conclusions will refer to evaluation of first product type. The evaluating competent authority (eCA) and BPC will only evaluate additional product type specific data. Labour AD desk officer in peer review phase (10 days additional): € 5 858 Support by legal unit (0.4 days): € 234 **Additional costs per dossier: € 6 092**
Years that costs will be allocated	**N+1:** evaluation & peer review, **N+2:** peer review.

AS09	Renewal of active substance approvals
Legal basis	Reg (EU) 528/2012, Art 10; Reg (EU) 528/2012, Art 13-15; Reg (EU) 528/2012, Art 75(1)a; Reg (EU) 528/2012, Art 76(1)b.
Short description	**Additional activities per product type (for both the first product- type and any additional product type) if the active substance is a candidate for substitution in accordance with Article 10 of Regulation (EU) No 528/2012**
Description of the activities performed by ECHA	ECHA organise the public consultation and report on its outcomes.
Costs related to the activities	Support for public consultation AD staff (5 additional days): € 2 929 Support for public consultation AST staff (2 additional days): € 1 172 **Additional costs per dossier: € 4 101**
Years that costs will be allocated	**N+1:** public consultation,

Table 3-4 **Annex I inclusion of an active substance**

AS10	Annex I inclusion of an active substance
Legal basis	CIR (EU) 88/2014, Art 3-5 Reg (EU) 528/2012, Art 7(2); Reg (EU) 528/2012, Art 28
Short description	**Activities for the first inclusion in Annex I of an active substance**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA accepts submission after payment of fees (T= 30 d) and informs applicant and the evaluating competent authority (eCA) accordingly. The evaluating competent authority (eCA) sends assessment report and conclusions of its evaluation to ECHA (T= 210-390 d (categories 1-5), 395-575 d (category 6)). ECHA coordinates and contributes to the commenting activities of the other MSCAs. The BPC working groups discuss the outstanding technical and scientific issues related to the draft assessment report in order to finalise it. Biocidal Products Committee (BPC) prepares the opinion of ECHA on the application. ECHA submits to the Commission the opinion on the inclusion of the active substance (T= 390-570 d (categories 1-5), 665-845 d (category 6)).
Costs related to the activities	**Activities of BPC start 210-575 d after the fee was received by ECHA** Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 238 Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. Labour AD officer evaluation phase (5 days): € 2 929 Labour AD officer peer review phase (25 days): € 14 645 Labour AST officer (4 days):€ 2 343.2 Support by legal unit (1.125 days): € 703 **Total costs per dossier: € 20 840**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, **N+1:** evaluation & peer review, **N+2:** peer review.

AS11	Annex I inclusion of an active substance
Legal basis	CIR (EU) 88/2014, Art 3-5 Reg (EU) 528/2012, Art 7(2); Reg (EU) 528/2012, Art 28
Short description	**Activities for the amendment of an inclusion of an active substance in Annex I**
Description of the activities performed by ECHA	See description of activities for the first inclusion in Annex I of an active substance.
Costs related to the activities	**Activities of BPC start 210-575 d after the fee was received by ECHA** Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. The evaluating competent authority (eCA) and BPC will only evaluate data specific to amendment. Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 146.5 Labour AD officer in evaluation phase (3 days): € 1 757.4 Labour AD officer in peer review phase (15 days): € 8 787 Labour AST officer (2 days):€ 1 171.6 Support by legal unit (0.8 days): € 469 **Total costs per dossier: € 12 331**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, **N+1:** evaluation & peer review, **N+2:** peer review.

Costs related to activities under Annex II

Table 3-5 **Pre-submission for Union authorisation**

UA01	Authorisation of biocidal products
Legal basis	Reg (EU) 528/2012, Art 43-44; Reg (EU) 528/2012, Art 76(1)b
Short description	**Pre-submission consultation for Union Authorisation**
Description of the activities performed by ECHA	ECHA receives submission via the ECHA Helpdesk (T= 0). The pre-submission serves to confirm whether: • the product falls within the scope of BPR; • the product has similar conditions of use across the EU; and • that the appropriate PT has been identified. ECHA organises the consultation of MSs and COM. ECHA informs the applicant of the outcome of the pre-submission consultation.
Costs related to the activities	Labour AD desk officer at pre-submission (5 days): € 2 929 Labour AST at pre-submission (2 days): € 1 171.6 Support by legal unit (0.125 days): € 73 **Total costs per dossier: € 4 174**
Years that costs will be allocated	**-N:** Pre submission consultation & Invoicing and financial reconciliation, **-N+1:** evaluation phase, **-N+2:** peer review & coordination MS checks of translations agreed SPC in all official languages.

Table 3-6 Union authorisation

UA02	Authorisation of biocidal products
Legal basis	Reg (EU) 528/2012, Art 43-44; Reg (EU) 528/2012, Art 76(1)b
Short description	**Activities per product not identical with (one of) the representative product(s) assessed for the purpose of the substance approval.**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA examines whether the active substance fulfils the criteria of candidates for substitution. ECHA accepts submission after payment of fees (T= 30 d) and informs applicant and the evaluating competent authority (eCA) accordingly. ECHA is informed about validation of application by the evaluating competent authority (eCA) (T= 60-150 d). The evaluating competent authority (eCA) sends assessment report and conclusions of its evaluation to ECHA (T= 425-695 d). ECHA coordinates and contributes to the commenting activities of the other MSCAs. The BPC working groups discuss the outstanding technical and scientific issues related to the draft assessment report in order to finalise it. Biocidal Products Committee (BPC) prepares the opinion of ECHA on the application and if active substance is considered candidate for substitution. ECHA submits to the Commission the opinion on the authorisation of the biocidal product (T= 605-875 d).
Costs related to the activities	**Activities of BPC start 425-695 d after the fee was received by ECHA, however activities in Working Groups can start earlier.** Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 219.7 Labour AD desk officer during evaluation phase (5 days): € 2 929 Labour AD desk officer at peer review phase[5] (25 days): € 14 645 Labour AST desk officer at peer review phase (4 days) € 2 343.2 AD coordinating MS checks of translations agreed SPC in all official languages (4 days): € 2 343.2 AST coordinating MS checks of translations agreed SPC in all official languages (2 days): € 1 171.6 Support legal unit (1.375 days): € 805 **Total costs per dossier: € 24 457**
Years that costs will be allocated	**-N:** Pre submission consultation & Invoicing and financial reconciliation, **-N+1:** evaluation phase, **-N+2:** peer review & coordination MS checks of translations agreed SPC in all official languages.

[5] by supporting eCA, BPC & working groups, evaluating eCA reports and comments MSCAs, writing down BPC opinion,

UA03	Authorisation of biocidal products
Legal basis	Reg (EU) 528/2012, Art 43-44; Reg (EU) 528/2012, Art 76(1)b
Short description	**Activities per product identical with (one of) the representative product(s) assessed for the purpose of the substance approval.**
Description of the activities performed by ECHA	See description of activities for granting of Union authorisation of product not identical with (one of) the representative product(s) assessed for the purpose of the substance approval
Costs related to the activities	**Activities of BPC start 425-695 d after the fee was received by ECHA** Labour: Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. Product was already evaluated during substance approval. Therefore labour of Biocidal Products Committee will be reduced. Labour AD desk officer submission (5 days): € 2 929 Labour AD desk officer at peer review phase (25 days): € 14 645 Labour AST desk (4 days) at peer review phase: € 2 343.2 AD coordinating MS checks of translations agreed SPC in all official languages (4 days): € 2 343.2 AST coordinating MS checks of translations agreed SPC in all official languages (2 days): € 1 171.6 Support legal unit (1.375 days): € 805 **Total costs per dossier: 24 237**
Years that costs will be allocated	**-N:** Pre submission consultation & Invoicing and financial reconciliation, **-N+1:** evaluation phase, **-N+2:** peer review & coordination MS checks of translations agreed SPC in all official languages.

UA04	Authorisation of biocidal products
Legal basis	Reg (EU) 528/2012, Art 43-44; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 23-24
Short description	**Additional activities per product when comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 is required**
Description of the activities performed by ECHA	See description of activities for granting of Union authorisation of product not identical with (one of) the representative product(s) assessed for the purpose of the substance approval. Comparative assessment carried out by evaluating authority.
Costs related to the activities	**Activities of BPC are finalised up to 180 days before the invoice for the additional fee is sent** by ECHA (the decision on substitution candidacy is made at final EC decision). Labour AD desk officer supporting the eCA in the comparative assessment, (5 days): € 2 929 Labour AST supporting the eCA in the comparative assessment, collecting data on alternative products in the other MS (3 days): € 1 757.4 **Additional costs per dossier: € 4 686**
Years that costs will be allocated	**-N:** evaluation phase

UA05	Authorisation of biocidal products
Legal basis	Reg (EU) 528/2012, Art 43-44; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 55(2)
Short description	**Additional activities per product when the requested authorisation is provisional in accordance with Article 55(2) of Regulation (EU) No 528/2012**
Description of the activities performed by ECHA	See description of activities for granting of Union authorisation of product not identical with (one of) the representative product(s) assessed for the purpose of the substance approval.
Costs related to the activities	**Activities of BPC start 425-695 d after the fee was received by ECHA** Labour: additional work to support both provisional authorisation and final authorisation. Labour AD desk officer (10 days): € 5 858 **Additional costs per dossier: € 5 858**
Years that costs will be allocated	**-N+1:** evaluation phase, **-N+2:** evaluation phase

UA06	Authorisation of biocidal product families
Legal basis	Reg (EU) 528/2012, Art 43-44; Reg (EU) 528/2012, Art 76(1)b
Short description	**Activities per product family**
Description of the activities performed by ECHA	See description of activities for granting of Union authorisation of product not identical with (one of) the representative product(s) assessed for the purpose of the substance approval
Costs related to the activities	**Activities of BPC start 425-695 d after the fee was received by ECHA, however activities in Working Groups can start earlier.** Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. Product family contains biocidal products having similar uses, the same active substances, similar composition with specified variations and similar levels of risk and efficacy. Several assessments must be performed to cover the different cases covered by the family. Therefore labour of Biocidal Products Committee will be increased compared to single biocidal product. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): €219.7 Labour AD desk officer during evaluation phase (10 days): € 5 858 Labour AD desk officer at peer review phase[6] (35 days): € 20 503 AD coordinating MS checks of translations agreed SPC in all official languages (4 days): € 2 343.2 Labour AST at peer review phase (4 days): € 2 343.2 AST coordinating MS checks of translations agreed SPC in all official languages (2 days): € 1 171.6 Support legal unit (1.375 days): € 805 **Total costs per dossier: € 33 244**
Years that costs will be allocated	**-N:** Pre submission consultation & Invoicing and financial reconciliation, **-N+1:** evaluation phase, **-N+2:** peer review & coordination MS checks of translations agreed SPC in all official languages.

[6] by supporting eCA, BPC & working groups, evaluating eCA reports and comments MSCAs, writing down BPC opinion,

UA07	Authorisation of biocidal product families
Legal basis	Reg (EU) 528/2012, Art 43-44; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 23-24
Short description	**Additional activities per family when comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 is required**
Description of the activities performed by ECHA	See description of activities for granting of Union authorisation of product not identical with (one of) the representative product(s) assessed for the purpose of the substance approval. Comparative assessment carried out by evaluating authority.
Costs related to the activities	**Activities of BPC are finalised up to 180 days before the invoice for the additional fee is sent** by ECHA (the decision on substitution candidacy is made at final EC decision). Labour: ECHA supports the eCA in the preparation of the comparative assessment. Labour AD desk officer supporting the eCA in the comparative assessment (7 days): € 4 1 00.6 Labour AST desk officer supporting the eCA in the comparative assessment (5 days): € 2 929 **Total costs ECHA: € 7 029**
Years that costs will be allocated	**-N:** evaluation phase

UA08	Authorisation of biocidal product families
Legal basis	Reg (EU) 528/2012, Art 43-44; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 55(2)
Short description	**Additional activities per family when the requested authorisation is provisional in accordance with Article 55(2) of Regulation (EU) No 528/2012**
Description of the activities performed by ECHA	See description of activities for granting of Union authorisation of product not identical with (one of) the representative product(s) assessed for the purpose of the substance approval
Costs related to the activities	**Activities of BPC start 425-695 d after the fee was received by ECHA** Labour: additional work to support both provisional authorisation and final authorisation. Labour AD desk officer (5 days): € 2 929 Labour AST desk officer (2 days): € 1 172 **Total costs ECHA: € 4 101**
Years that costs will be allocated	**-N+1:** evaluation phase, **-N+2:** evaluation phase

UA09	Authorisation of biocidal product families
Legal basis	Reg (EU) 528/2012, Art 17(6)
Short description	**Activities per additional product within a biocidal product family notified to the Agency; Article 17(6)**
Description of the activities performed by ECHA	ECHA receives notification via R4BP and informs applicant of fees to be paid. (T= 0). ECHA accepts notification after payment of fees (T= 30 d), checks that the notified product falls within the accepted variations of the family and informs applicant accordingly.
Costs related to the activities	**Activities of ECHA start when the fee is received by ECHA** Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 146 Labour AD desk officer at submission (1 day): € 586 **Total costs per notification: € 732**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase.

UA10	Authorisation of a same biocidal product
Legal basis	CIR (EU) 414/2013, Art 4 & 6; Reg (EU) 528/2012, Art 17(6); Reg (EU) 528/2012, Art 43-44
Short description	**Activities per product constituting a 'same product' within the meaning of Commission Implementing Regulation (EU) No 414/2013 of 6 May 2013 specifying a procedure for the authorisation of same biocidal products in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA accepts notification after payment of fees (T= 30 d) and informs applicant accordingly. ECHA validates the application provided that the information indicated in Article 2 has been submitted T=60-150 d). ECHA coordinates the checking of the translation of the SPC by the MSCAs.
Costs related to the activities	**Activities of ECHA start when the fee is received by ECHA** Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer (5 days): € 2 929 Labour AST desk officer during evaluation phase (2 days): € 1 172 **Total costs per dossier: € 4 247** Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer (8 days): € 4 686 Labour AST desk officer during evaluation phase (3 days): € 1 757 **Total costs per dossier for BP family: € 7 249**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase, coordination MS checks of translations agreed SPC in all official languages.

Table 3-7 Amendments of Union Authorisation

UA11	Amendments of Union authorisations
Legal basis	Reg (EU) 528/2012, Art 50(2); Reg (EU) 354/2013, Art 2
Short description	**Activities per request on the classification of a change of an authorised product or product family in accordance with Regulation (EU) No 354/2013.**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA accepts submission after payment of fees (T= 30 d) and informs applicant accordingly. ECHA delivers its opinion to the applicant and publishes the opinion (T=75d)
Costs related to the activities	**Activities of ECHA start when the fee is received by ECHA.** If the recommendation is to classify the change as an administrative or minor change, the fee for the request shall be deducted from the subsequent application or notification in accordance with Regulation (EU) No 354/2013. Labour: ECHA assess the considered change and classify it as administrative, minor or major. Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer (10 days): € 5 858 Labour AST desk officer (2 days): € 1 172 Support by legal unit (0.5 days): € 293 **Total costs per dossier: € 7 469**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase.

UA12	Amendments of Union authorisations
Legal basis	Reg (EU) 528/2012, Art 50(2); Reg (EU) 354/2013 (Art 13)
Short description	**Activities per application for a major change of an authorised product or product family**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA accepts submission after payment of fees (T= 30 d) and informs applicant and competent authority accordingly. ECHA is informed about validation of application by the evaluating competent authority (eCA) (T= 60-150 d). The evaluating competent authority (eCA) sends assessment report and conclusions of its evaluation to ECHA (T= 240-420 d). ECHA coordinates and contributes to the commenting activities of the other MSCAs. The BPC working groups discuss the outstanding technical and scientific issues related to the draft assessment report in order to finalise it. Biocidal Products Committee (BPC) prepares the opinion of ECHA on the application. ECHA submits to the Commission the opinion on the proposed change. In case of a favourable opinion, ECHA shall indicate whether the proposed change would require an amendment of the authorisation (T= 330-510 d). The Agency shall inform the applicant of its opinion and make it available in the Register for Biocidal Products. Where relevant, ECHA transmits to the Commission, in all the official languages of the Union, the revised summary of the biocidal product characteristics (prepared by the applicant), as referred to in Article 22(2) of Regulation (EU) No 528/2012 (T= 360-540 d).

Costs related to the activities	**Activities of BPC start 240-420 d after the fee was received by ECHA, however activities in the Working Groups can start earlier.** Travel costs and accommodation of Members of the Biocidal Product Committee are paid by ECHA. Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. The evaluating competent authority (eCA) and BPC will only evaluate data specific to major change Therefore labour of Biocidal Products Committee will be reduced compared to application for Union authorisation. Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer during evaluation phase (3 days): € 1 757 Labour AD desk officer at peer review phase[7] (20 days): € 11 716 Labour AST desk officer at peer review phase (4 days): € 2 343 AD coordinating MS check of translations agreed SPC in all official languages (4 days): € 2 343 AST coordinating MS check of translations agreed SPC in all official languages (2 days): € 1 172 Support legal unit (1.375 days): € 805 **Total costs per dossier for BP: €20 283** Work for BP family: Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer during evaluation phase (5 days): € 2 929 Labour AD desk officer at peer review phase[8] (25 days): € 14 645 Labour AST desk officer at peer review phase (5 days): € 2 929 AD coordinating MS check of translations agreed SPC in all official languages (4 days): € 2 343 AST coordinating MS check of translations agreed SPC in all official languages (2 days): € 1 172 Support legal unit (1.375 days): € 805 **Total costs per dossier for BP family: € 24 969**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, **-N+1:** evaluation phase, **-N+2:** peer review & coordination MS checks of translations agreed SPC in all official languages.

[7] by supporting eCA, BPC & working groups, evaluating eCA reports and comments MSCAs, writing down BPC opinion,
[8] by supporting eCA, BPC & working groups, evaluating eCA reports and comments MSCAs, writing down BPC opinion,

UA13	Amendments of Union authorisations
Legal basis	Reg (EU) 528/2012, Art 50(2); Reg (EU) 354/2013 (Art 12)
Short description	**Activities per application for a minor change of an authorised product or product family**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA accepts submission after payment of fees (T= 30 d) and informs applicant accordingly. ECHA validates application and informs applicant accordingly (T= 60-105 d). ECHA coordinates and contributes to the commenting activities of the other MSCAs. The BPC working groups discuss the outstanding technical and scientific issues related to the draft assessment report in order to finalise it. Biocidal Products Committee (BPC) prepares the opinion of ECHA on the application. ECHA submits to the Commission the opinion on the proposed change. In case of a favourable opinion, ECHA shall indicate whether the proposed change would require an amendment of the authorisation (T= 150-240 d). The Agency shall inform the applicant of its opinion and make it available in the Register for Biocidal Products. ECHA transmits to the Commission, in all the official languages of the Union, the revised summary of the biocidal product characteristics (prepared by the applicant), as referred to in Article 22(2) of Regulation (EU) No 528/2012 (T= 180-270 d).
Costs related to the activities	**Activities of ECHA start when the fee is received by ECHA** Travel costs and accommodation of Members of the Biocidal Product Committee are paid by ECHA. Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. BPC will only evaluate data specific to minor change Therefore labour of Biocidal Products Committee will be reduced compared to application for major change. Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer (15 days): € 8 787 Labour AST desk officer (2 days): € 1 172 AD coordinating MS check of translations agreed SPC in all official languages (3 days): € 1 757 AST coordinating MS check of translations agreed SPC in all official languages (2 days): € 1 172 Support legal unit (0.5 days): € 293 **Total costs per dossier for BP: €13 327** Work for BP family: Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer (25 days): € 14 645 Labour AST desk officer (4 days): € 2 343 AD coordinating MS check of translations agreed SPC in all official languages (5 days): € 2 929 AST coordinating MS check of translations agreed SPC in all official languages (2 days): € 1 172 Support legal unit (0.5 days): € 293 **Total costs per dossier for BP family: € 21 528**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, **-N+1:** evaluation phase, peer review & coordination MS checks of translations agreed SPC in all official languages.

UA14	Amendments of Union authorisations
Legal basis	Reg (EU) 528/2012, Art 50(2); Reg (EU) 354/2013 (Art 11)
Short description	**Activities per notification of an administrative change of an authorised product or product family**
Description of the activities performed by ECHA	ECHA receives notification via R4BP and informs applicant of fees to be paid. (T= 0). ECHA accepts notification after payment of fees (T= 30 d) and informs applicant accordingly. ECHA prepares and submits to the Commission an opinion on the proposed change (T= 60 d). ECHA transmits to the Commission, in all the official languages of the Union, the revised summary of the biocidal product characteristics (prepared by the applicant), as referred to in Article 22(2) of Regulation (EU) No 528/2012.
Costs related to the activities	**Activities of ECHA start when the fee is received by ECHA**. Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer (5 days): € 2 929 Labour AST desk officer (1 day): € 585.8 **Total costs per dossier: € 3 661**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase.

UA15	Renewal of Union Authorisation
Legal basis	Reg (EU) 528/2012, Art 45(3)
Short description	**Activities per single product**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA accepts submission after payment of fees (T= 30 d) and informs applicant and the evaluating competent authority (eCA) accordingly. ECHA is informed by the evaluating competent authority (eCA) whether, in the light of current scientific knowledge, a full evaluation of the application for renewal is necessary. (T=60 d) If a full evaluation is not necessary ECHA receives a recommendation on the renewal of authorisation from the evaluating competent authority (eCA) (T=210 d). ECHA prepares and submits to the Commission an opinion on the renewal of the Union authorisation (T= 390 d)
Costs related to the activities	**Activities of ECHA start 180 d after the fee was received by ECHA**. Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer during evaluation phase (3 days): € 1 757 Labour AD desk officer at peer review phase[9] (10 days): € 5 858 Labour AST desk officer at peer review phase (3 days): € 1 757 AD coordinating MS checks of translations agreed SPC in all official languages (4 days): € 2 343 AST coordinating MS checks of translations agreed SPC in all official languages (2 days): € 1 172 Support legal unit (1.375 days): € 805 **Total costs per dossier: € 13 839**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, **-N+1:** evaluation phase, peer review & coordination MS checks of translations agreed SPC in all official languages. **-N+2:** peer review & coordination MS checks of translations agreed SPC in all official languages.

[9] by supporting eCA, BPC & working groups, evaluating eCA reports and comments MSCAs, writing down BPC opinion,

UA16	Renewal of Union Authorisation
Legal basis	Reg (EU) 528/2012, Art 45(3); Reg (EU) 528/2012, Art 14(1)
Short description	**Additional activities per product in case a full evaluation is found necessary in accordance with Article 14(1) of Regulation (EU) No 528/2012**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). ECHA accepts submission after payment of fees (T= 30 d) and informs applicant and the evaluating competent authority (eCA) accordingly. ECHA is informed by the evaluating competent authority (eCA) that a full evaluation of the application for renewal is necessary. (T=60 d) The evaluating competent authority (eCA) sends assessment report and conclusions of its evaluation to ECHA (T= 335 d). ECHA coordinates and contributes to the commenting activities of the other MSCAs. The BPC working groups discuss the outstanding technical and scientific issues related to the draft assessment report in order to finalise it. Biocidal Products Committee (BPC) prepares the opinion of ECHA on the application. ECHA submits to the Commission the opinion on the approval of the active substance (T= 505 d).
Costs related to the activities	**Activities of BPC start 305 d after the first fee was received by ECHA and 275 d after the additional fee was received.** Travel costs and accommodation of Members of the Biocidal Product Committee are paid by ECHA. Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. The evaluating competent authority (eCA) and BPC will evaluate new relevant data generated since previous approval and whether the conclusions of the previous assessment of the Union Authorisation remain valid. Therefore labour of Biocidal Products Committee will be reduced compared to initial application. Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer during evaluation phase (2 days): € 1 172 Labour AD desk officer at peer review phase[10] (15 days): € 8 787 Labour AST desk officer at peer review phase (1 day): € 586 **Additional costs per dossier: € 10 691**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, **-N+1:** evaluation phase, **-N+2:** peer review & coordination MS checks of translations agreed SPC in all official languages.

[10] by supporting eCA, BPC & working groups, evaluating eCA reports and comments MSCAs, writing down BPC opinion,

UA17	Renewal of Union Authorisation
Legal basis	Reg (EU) 528/2012, Art 45(3); Reg (EU) 528/2012, Art 23
Short description	**Additional fee per product when comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 is required**
Description of the activities performed by ECHA	See description of activities for renewal of Union authorisation. Comparative assessment carried out by evaluating authority.
Costs related to the activities	**Activities of BPC are finalised up to 180 days before the invoice for the additional fee is sent by ECHA (the decision on substitution candidacy is made at final EC decision).** Labour: ECHA support the comparative assessment by the eCA. Labour AD desk officer during evaluation phase (5 days): € 2 929 Labour AST desk officer during evaluation phase (3 days): €1 757 **Additional costs per dossier: € 4 686**
Years that costs will be allocated	**-N:** evaluation phase

UA18	Renewal of Union Authorisation biocidal product families
Legal basis	Reg (EU) 528/2012, Art 45(3)
Short description	**Activities per product family**
Description of the activities performed by ECHA	See description of activities for renewal of Union product authorisation.
Costs related to the activities	**Activities of ECHA start 180 d after the fee was received by ECHA.** Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. Product family contains biocidal products having similar uses, the same active substances, similar composition with specified variations and similar levels of risk and efficacy. Similarity of the products must be checked. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour AD desk officer during evaluation phase (5 days): € 2 929 Labour AD desk officer at peer review phase[11] (15 days): € 8 787 Labour AST desk officer at peer review phase (3 days): € 1 757 AD coordinating MS check of translations agreed SPC in all official languages (3 days): € 1 757 AST coordinating MS check of translations agreed SPC in all official languages (2 days): € 1 172 Support legal unit (1.375 days): € 805 **Total costs per dossier: € 17 427**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, **-N+1:** evaluation phase, peer review & coordination MS checks of translations agreed SPC in all official languages. **-N+2:** peer review & coordination MS checks of translations agreed SPC in all official languages.

[11] by supporting eCA, BPC & working groups, evaluating eCA reports and comments MSCAs, writing down BPC opinion,

UA19	Renewal of Union Authorisation biocidal product families
Legal basis	Reg (EU) 528/2012, Art 45(3); Reg (EU) 528/2012, Art 14(1)
Short description	**Additional activities per product family in case a full evaluation is found necessary in accordance with Article 14(1) of Regulation (EU) No 528/2012**
Description of the activities performed by ECHA	See description of activities for renewal of Union product authorisation.
Costs related to the activities	**Activities of BPC start 305 d after the first fee was received by ECHA and 275 d after the additional fee was received.** Travel costs and accommodation of Members of the Biocidal Product Committee are paid by ECHA. Labour: ECHA experts comment on the reports submitted by the eCAs together with the other MSCAs. Product family contains biocidal products having similar uses, the same active substances, similar composition with specified variations and similar levels of risk and efficacy. Similarity of the products must be checked. Therefore labour of Biocidal Products Committee will be increased compared to single biocidal product. Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 147 Labour AD desk officer during evaluation phase (3 days): € 1 757 Labour AD desk officer at peer review phase[12] (20 days): € 11 716 AD coordinating MS check of translations agreed SPC in all official languages (1 day): € 585.8 AST coordinating MS check of translations agreed SPC in all official languages (1 day): € 585.8 **Additional costs per dossier: € 14 791**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, **-N+1:** evaluation phase, **-N+2:** peer review & coordination MS checks of translations agreed SPC in all official languages.

UA20	Renewal of Union Authorisation biocidal product families
Legal basis	Reg (EU) 528/2012, Art 45(3); Reg (EU) 528/2012, Art 23
Short description	**Additional fee per product family when comparative assessment in accordance with Article 23 of Regulation (EU) No 528/2012 is required**
Description of the activities performed by ECHA	See description of activities for renewal of Union authorisation. Comparative assessment carried out by evaluating authority.
Costs related to the activities	**Activities of BPC are finalised up to 180 days before the invoice for the additional fee is sent by ECHA (the decision on substitution candidacy is made at final EC decision).** Travel costs and accommodation of Members of the Biocidal Product Committee are paid by ECHA. Labour: ECHA support the comparative assessment by the eCA. Labour AD desk officer (7 days): € 4 100 Labour AST desk officer (5 days): € 2 929 **Additional costs per dossier: € 7 029**
Years that costs will be allocated	**-N:** evaluation phase

[12] by supporting eCA, BPC & working groups, evaluating eCA reports and comments MSCAs, writing down BPC opinion,

Activities related to Annex III

Table 3-8 **Technical equivalence**

TE01	Technical equivalence
Legal basis	Assessment of technical equivalence: Article 54(3) Reg (EU) 528/2012, Art 76(1)c
Short description	**Activities, when difference between the active substance sources is limited to a change in manufacturing location, and application is based solely on analytical data**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0) ECHA accepts submission after payment of fees (T= 30 d) and informs applicant accordingly. ECHA consult the original eCA on the establishment of the reference specifications and the underlying analytical data. ECHA carries out assessment of technical equivalence and informs applicant and Member States about its decision (T= 120-300 d)
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA.** Labour: Evaluation of analytical data: evaluation batch analysis and analytical methods used, check whether manufacturing process is similar. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour desk officers (6 days): € 3 515 Labour AST (2 day): € 1 172 Support by legal unit (0.375 days): € 220 **Total costs per dossier: € 5 126**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase

TE02	Technical equivalence
Legal basis	Assessment of technical equivalence: Article 54(3) Reg (EU) 528/2012, Art 76(1)c
Short description	**Activities, when difference between the active substance sources goes beyond a change in the manufacturing location, and application is based solely on analytical data**
Description of the activities performed by ECHA	See description of activities when difference between the active substance sources is limited to a change in manufacturing location, and application is based solely on analytical data
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA**. Labour: Evaluation of analytical data: evaluation of batch analysis, analytical methods, manufacturing process and potential new impurities. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour desk officers (6 days): € 3 515 Labour AST (2 day): € 1 172 Support by legal unit (0.375 days): € 220 **Total costs per dossier: € 5 126**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase

TE03	Technical equivalence
Legal basis	Assessment of technical equivalence: Article 54(3) Reg (EU) 528/2012, Art 76(1)c
Short description	**Activities, when previous conditions are not met**
Description of the activities performed by ECHA	See description of activities when difference between the active substance sources is limited to a change in manufacturing location, and application is based solely on analytical data
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA**. Labour: Evaluation of analytical data: evaluation of batch analysis, analytical methods, manufacturing process and potential new impurities. Risk assessment new impurities and/or impurity levels. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour desk officers AD evaluating technical equivalence (22 days): € 12 888 Labour AST (2 days): € 1 172 Support by legal unit (0.625 days): € 366 **Total costs per dossier: € 14 645**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase

Table 3-9 Annual fees for Union Authorisation

UA21	Annual fee for biocidal products authorised by the Union
Legal basis	Reg (EU) 528/2012, Art 80(1)a
Short description	**Annual activities per Union authorisation of a biocidal product**
Description of the activities performed by ECHA	ECHA staff invoices an annual fee for the Biocidal Products which hold a Union Authorisation.
Costs related to the activities	Invoicing and financial reconciliation by ECHA AD staff:€ 146
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation

UA22	Annual fee for biocidal products authorised by the Union
Legal basis	Reg (EU) 528/2012, Art 80(1)a
Short description	**Annual activities per Union authorisation of a biocidal product family**
Description of the activities performed by ECHA	ECHA staff invoices an annual fee for the Biocidal Product Families which hold a Union Authorisation
Costs related to the activities	Invoicing and financial reconciliation by ECHA AD staff: € 146
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation

Table 3-10 Mutual recognition

MR01	Mutual recognition
Legal basis	Reg (EU) 528/2012, Art 33(1)f; Reg (EU) 528/2012, Art 34(2); Reg (EU) 528/2012, Art 75(1)f; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 80(1)a
Short description	**Activities per product or product family concerned by an application for mutual recognition, per Member State where mutual recognition is sought**
Description of the activities performed by ECHA	Application is submitted directly to the competent evaluating authority. ECHA performs the tasks relating to the acceptance of the application and in case of questions ECHA provides the secretariat of the coordination group. If the coordination group fails to reach an agreement the Commission may ask ECHA for an opinion on scientific or technical questions raised by Member States T= 210 -575 d). The BPC prepares within 120 days the opinion of ECHA on scientific and technical matters concerning mutual recognition.
Costs related to the activities	Labour: Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 146 **Total:€ 146** .
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, **-N+1:** optional: evaluation phase & peer review
MR03	Mutual recognition
Legal basis	Reg. (EU) 492/2014 Reg (EU) 528/2012, Art 33(1)f; Reg (EU) 528/2012, Art 34(2); Reg (EU) 528/2012, Art 75(1)f; Reg (EU) 528/2012, Art 76(1)b; Reg (EU) 528/2012, Art 80(1)a
Short description	**Activities per product or product family concerned by an application for renewal of mutual recognition, per Member State where mutual recognition is sought**
Description of the activities performed by ECHA	Application is submitted directly to the competent evaluating authority. ECHA performs the tasks relating to the acceptance of the application and invoicing.
Costs related to the activities	Labour: **Total:€ 0**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation

Table 3-11 Appeal & Legal litigation

AP01	Appeal
Legal basis	Reg (EU) 528/2012, Art 77(1)f; Reg (EC) No 1907/2006 , Art 91(1-2), 93 & 94
Short description	**Activities per appeal**
Description of the activities performed by ECHA	The appeal, together with the statements of the grounds thereof, shall be filed in writing to ECHA within three months of the notification of the decision appealed against. If, after consultation with the Chairman of the Board of Appeal, the Executive Director considers the appeal to be admissible and well-founded he may rectify the decision within 30 days of the appeal being filed. Otherwise the Chairman of the Board of Appeal shall examine whether the appeal is admissible within 30 days of the appeal being filed. ECHA has the opportunity to lodge the defence within two months after being notified of the notice of appeal. The Board of Appeal considers the appeal and the defence to reach a decision on the appeal and informs the appellant and ECHA accordingly. If the decision is favourable to the appellant, ECHA has to re-process the activity on which its decision was successfully appealed in order to reach a new decision.
Costs related to the activities	Invoicing and financial reconciliation by ECHA AD staff (0.25 days): € 146 Labour AD desk officers supporting the BoA and the members of the BoA (80 days): € 46 854 Labour AD desk officer defending unit (10 days): € 5 858 Support legal unit (40 days): € 23 432 **Total costs per dossier: € 76 299**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, consideration of appeal

AP02	Appeal
Legal basis	Reg (EU) 528/2012, Art 77(1)f; Reg (EC) No 1907/2006 , Art 91(1-2), 93 & 94
Short description	**Legal litigation in court**
Description of the activities performed by ECHA	When an appeal is brought to the Board of Appeal of ECHA as outlined above or an appeal that is not related to any of the decisions listed which have to be brought to the BoA of ECHA first, the action can be taken to bring the appeal to the European Court of Justice. ECHA then needs to defend the decision on the base of which the appeal has been made.
Costs related to the activities	Labour per court case for the defending operational unit (15 days): € 8 787 Labour per court case for the legal unit (32 days): €18 745 **Total costs per case: € 27 532**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, consideration of appeal

Table 3-12 Alternative supplier application under art. 95

AS12	Alternative supplier application
Legal basis	Reg (EU) 528/2012, Art 95(1)
Short description	**Activities per submission of a letter of access to a dossier already found complete by the Agency or an evaluating Competent Authority**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). After payment of fees (T= 30 d) ECHA verifies whether the submission complies with Art 95 and informs applicant of its draft decision. The applicant is able to comment and if necessary provide additional data. ECHA takes into account the comments and/or the additional data to finalise its assessment and reach a final decision. ECHA informs the applicant accordingly.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA.** Labour: ECHA checks validity of letter of access and whether dossier referred to is indeed already found complete. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour AD desk officer checking validity LoA & dossier referred to (4 days): € 2 343 Labour AST desk officer (1 day): € 586 Support legal officer (0.3125 days): € 183 **Total costs per dossier: € 3 332**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase

AS13	Alternative supplier application
Legal basis	Reg (EU) 528/2012, Art 95(1)
Short description	**Activities per submission of a letter of access to part of a dossier already found complete by the Agency or an evaluating Competent Authority, together with complementary data**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). After payment of fees (T= 30 d) ECHA verifies whether the submission complies with Art 95 and informs applicant of its draft decision. The applicant is able to comment and if necessary provide additional data. ECHA takes into account the comments and/or the additional data to finalise its assessment and reach a final decision. ECHA informs the applicant accordingly.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA.** Labour: ECHA checks validity of letter of access and whether the dossier referred to (partly) is indeed already found complete. In addition ECHA checks whether the parts of the dossier referred to together with the complementary data submitted comply with Annex II to Reg (EU) 528/2012 or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive. Complementary data are not evaluated. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour AD desk officer checking validity LoA & dossier referred to (9 days): € 5 272 Labour AST desk officer (1 day): € 586 Support legal officer (0.6875 days): € 403 **Total costs per dossier: € 6 480**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase

AS14	Alternative supplier application
Legal basis	Reg (EU) 528/2012, Art 95(1)
Short description	**Activities per submission of a new dossier**
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of fees to be paid. (T= 0). After payment of fees (T= 30 d) ECHA verifies whether the submission complies with Art 95 and informs applicant of its draft decision. The applicant is able to comment and if necessary provide additional data. ECHA takes into account the comments and/or the additional data to finalise its assessment and reach a final decision. ECHA informs the applicant accordingly.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA.** Labour: ECHA checks whether the new dossier submitted complies with Annex II to Reg (EU) 528/2012 or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive. The new dossier is not evaluated. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour AD desk officer checking validity LoA & dossier referred to (9 days): € 5 272 Labour AST desk officer (1 day): € 586 Support legal officer (0.6875 days): € 403 **Total costs per dossier: € 6 480**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase

Table 3-13 Request for confidentiality

CO01	Request for confidentiality
Legal basis	Reg (EU) 528/2012, Art 66(4) & 67(3-4)
Short description	**Activities per item for which confidentiality is requested**
Description of the activities performed by ECHA	Any person submitting information related to an active substance or a biocidal product to the Agency or a competent authority for the purposes of this Regulation may request that the information in Article 67(3) and (4) not be made available, including a justification as to why the disclosure of the information could be harmful for that person's commercial interests or those of any other party concerned. ECHA can also provide support to MSCAs when they are asked to check for confidentiality. In these cases, ECHA does not receive a fee.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA.** Labour: ECHA checks whether the submitted justification is valid in accordance with Article 66(4). Follow up with companies on the confidentiality claims. ECHA is responsible for the development and implementation of confidentiality assessment practices. Furthermore, ECHA needs to inform and update MSCAs on the received claims and its decision on their validity. Invoicing and financial reconciliation by ECHA AD staff (0.625 days): € 366 AD staff (0.5 days): € 293 Support by legal unit (0.125 days): € 73 **Total costs of request: € 403**
Years that costs will be allocated	**-N:** Invoicing and financial reconciliation, evaluation phase

Costs related to activities under the Review Programme

Table 3-14 Review Programme

RP01	Review Programme
Legal basis	Reg. (EU) 528/2012, art. 89 & 95
Short description	**Overall management of the review programme**
Description of the activities performed by ECHA	The head of unit of the Biocides Assessment unit oversees the management of the Review Programme. Other units within ECHA are also significantly involved and a number of directors as well.
Costs related to the activities	There is one full time AD working on the overall management of the RP. Labour AD: € 137 707 **Total cost of management: € 128 874**
Years that costs will be allocated	**N**: overall management

RP02	Review Programme
Legal basis	Reg. (EU) 528/2012, art. 89 & 95 Dir. 98/8/EC, art. 11
Short description	**Approval of AS submitted under the BPD (new and existing Active Substances)**
Description of the activities performed by ECHA	Cf. approval of active substance
Costs related to the activities	The annual costs amount to the number of dossiers processed each year (50 for the Review Programme and 8 for new active substance applications submitted under the BPD for the years 2016 to 2018) multiplied by the average cost per dossier, based upon the assumption that 30 % of the dossiers are candidates for substitution (€ 21 300 + 30 % of € 4 200 = € 22 560). The overall annual costs for 2016 – 2018 amount to € 1 308 480. The corresponding number of staff is calculated in a similar way: (50+8)*number of staff per dossier. Labour of AD desk officer at public consultation phase (5 days): € 2 929 Labour of AD desk officer at public consultation phase (25 days): € 14 645 Labour AST desk officer for peer review(4 days): € 2 343 Support for public consultation AD staff per dossier (1.5 days): € 879 Support for public consultation AST staff per dossier (0.6 day): € 351 Support by legal unit: € 703 **Total costs: 21 850**
Years that costs will be allocated	**N+1:** public consultation & peer review, **N+2:** peer review.

RP03	Review Programme
Legal basis	Reg. (EU) 1062/2014, art. 17
Short description	**Notification in accordance with art. 17 of Reg. (EU) 1062/2014**
Description of the activities performed by ECHA	ECHA assess the compliance of the notification with the data requirements defined in the legislation. N.B.: The fee received for the notification under this article is subsequently deducted from the corresponding active substance application, submitted at the latest two years after the positive decision by ECHA.
Costs related to the activities	Invoicing and financial reconciliation (0.25 days): € 156 Labour of AD desk officer (5 days): € 3 120 Labour AST desk officer (1 day): € 625 **Total cost per notification: €3 661**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, evaluation phase

Table 3-15 **Art. 95**

RP04	Review Programme
Legal basis	Reg. (EU) 528/2012, art. 95
Short description	**Article 95 list management**
Description of the activities performed by ECHA	ECHA is responsible for the publication of the list of relevant substances and the respective substance and product suppliers, in accordance with Article 95 of the Biocidal Products Regulation (BPR), as amended by Regulation (EU) No 334/2014 of 11 March 2014. ECHA thus takes upon them to keep the list up to date and correct.
Costs related to the activities	Labour AD desk officer (66 days): € 38 662 Labour AST desk officer (66 days): € 38 662 **Total cost: € 77 324**
Years that costs will be allocated	**N:** keeping the list up to date and correct

Costs related to the conducting of checks and drafting of opinions

Table 3-16 **SME status check**

SC01	SME status check
Legal basis	Reg. (EU) 528/2012, recital 8
Short description	**Checking of the status of SME for applications**
Description of the activities performed by ECHA	A company can submit a request for an SME status check through R4BP3. Within 45 days of receipt of all the relevant elements (requests can be still made by ECHA after the first submit of documents), the Agency shall decide what SME status, if any, can be recognised. A recognition of an enterprise as an SME shall be valid for applications submitted under Regulation (EU) No 528/2012 for two years. An appeal may be brought, in accordance with Article 77 of Regulation (EU) No 528/2012 against a decision taken by the Agency on the company's SME status..
Costs related to the activities	Labour AD desk officer (1.5 days): € 879 **Total costs per check: € 879**
Years that costs will be allocated	**N:** evaluation phase

Table 3-17 Chemical similarity

CS01	Chemical similarity
Legal basis	Management Board Decision 31/2013
Short description	Comparison of one source with an active substance (existing or new) under evaluation under BPD or BPR. Temporary reference source exists.
Description of the activities performed by ECHA	ECHA receives submission via R4BP and informs applicant of the possibility to process the request, of the target processing time and of fees to be paid. (T= 0). ECHA accepts submission after payment of fees (T= 30 d) and informs applicant accordingly. ECHA (secretariat) carries out assessment and informs applicant about its decision.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA**. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour AD desk officer (5 days): € 2 929 Labour AST desk officer (2 days): € 1 172 Support by legal unit (0.375 days): € 220 **Total costs per check: € 4 540**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, evaluation phase

CS02	Chemical similarity
Legal basis	Management Board Decision 31/2013
Short description	Comparison of one source with an active substance (existing or new) under evaluation under BPD or BPR. Temporary reference source does not exist and only one participant has submitted a dossier under the Review Programme for existing active substances or under new active substance approval (Article 7 of the BPR or Article 11 of BPD)
Description of the activities performed by ECHA	See description for activities on comparison when temporary reference source exists.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA**. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour AD desk officer (7 days): € 4 101 Labour AST desk officer (2 days): € 1 172 Support by legal unit (0.375 days): € 220 **Total costs per check: € 5 711**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, evaluation phase

CS03	Chemical similarity
Legal basis	Management Board Decision 31/2013
Short description	Comparison of one source with an active substance (existing or new) under evaluation under BPD or BPR. Temporary reference source does not exist and only one participant has submitted a dossier under the Review Programme for existing active substances or under new active substance approval (Article 7 of the BPR or Article 11 of BPD)
Description of the activities performed by ECHA	See description for activities on comparison when temporary reference source exists.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA**. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour AD desk officer (7 days): € 4 101 Labour AST desk officer (2 days): € 1 172 Support by legal unit (0.375 days): € 220 **Total costs per check: € 5 711**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, evaluation phase

CS04	Chemical similarity
Legal basis	Management Board Decision 31/2013
Short description	Activities per additional dossier
Description of the activities performed by ECHA	See description for activities on comparison when temporary reference source exists.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA**. Labour AD desk officer (2 days): € 1 171 Labour AST desk officer (1 days): € 586 **Additional costs per check: € 1 757**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, evaluation phase

CS05	Chemical similarity
Legal basis	Management Board Decision 31/2013
Short description	Comparison of two or more sources of an active substance which is not yet under evaluation under BPD or BPR. Two datasets submitted for comparison.
Description of the activities performed by ECHA	See description for activities on comparison when temporary reference source exists.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA**. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour AD desk officer (5 days): € 2 929 Labour AST desk officer (2 days): € 1 172 Support by legal unit (0.375 days): € 220 **Total costs per check: € 4 540**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, evaluation phase

CS06	Chemical similarity
Legal basis	Management Board Decision 31/2013
Short description	Comparison of two or more sources of an active substance which is not yet under evaluation under BPD or BPR. Three or more datasets submitted for comparison.
Description of the activities performed by ECHA	See description for activities on comparison when temporary reference source exists.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA**. Invoicing and financial reconciliation by ECHA AD staff (0.375 days): € 220 Labour AD desk officer (5 days): € 2 929 Labour AST desk officer (2 days): € 1 172 Support by legal unit (0.375 days): € 220 **Total costs per check: € 4 540**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, evaluation phase

CS07	Chemical similarity
Legal basis	Management Board Decision 31/2013
Short description	Activities per additional dataset to CS06.
Description of the activities performed by ECHA	See description for activities on comparison when temporary reference source exists.
Costs related to the activities	**Activities of ECHA start immediately after the fee was received by ECHA**. Labour AD desk officer (7 days): € 4 101 Labour AST desk officer (2 days): € 1 171 **Total costs per check: € 5 272**
Years that costs will be allocated	**N:** Invoicing and financial reconciliation, evaluation phase

Table 3-18 MR disagreements

MR02	Mutual Recognition disagreements/opinions
Legal basis	Reg. (EU) 528/2012, art. 38
Short description	**Drafting of opinions on MR disagreements**
Description of the activities performed by ECHA	Where requested so by the European Commission, ECHA prepares an opinion to address the disagreement.
Costs related to the activities	Labour AD desk officer (25 days): € 14 645 Labour AST desk officer (4 days): € 2 343 Support by legal unit (1.125 days):€ 659 **Total cost per opinion: € 17 647**
Years that costs will be allocated	**N:** evaluation phase

Table 3-19. Other opinions

OP01	Other opinions
Legal basis	
Short description	**Drafting of other opinions**
Description of the activities performed by ECHA	Where requested so by the European Commission or by a MSCA, ECHA prepares an opinion on a technical or scientific issue.
Costs related to the activities	Labour AD desk officer (25 days): €14 645 Labour AST desk officer (4 days): € 2 343 Support by legal unit (1.125 days):€ 659 **Total cost per opinion: €17 647**
Years that costs will be allocated	**N:** evaluation phase

Table 3-20. Data-sharing

DS01	Data-sharing
Legal basis	Reg. (EU) 528/2012, art. 62(1)
Short description	**Supporting data-sharing inquiries**
Description of the activities performed by ECHA	After the submission of an inquiry for data – sharing, ECHA provides the prospective applicants with the contact details of the data submitter to allow them to proceed with negotiations with the data owner on the sharing of the data. In parallel, ECHA informs the data submitter about an inquiry on their active substance or BP.
Costs related to the activities	**The overall cost depends on the number of inquiries. Cost per inquiry:** **€ 37**
Years that costs will be allocated	**N:** evaluation phase

DS02	Data-sharing
Legal basis	Reg. (EU) 528/2012, art. 63(3)
Short description	**Data-sharing disputes**
Description of the activities performed by ECHA	When after a data – sharing inquiry was submitted, parties fail to reach an agreement, an applicate can file a data sharing dispute claim with ECHA. ECHA assesses the parties' respective efforts to reach such an agreement and takes a decision to grant or not to grant permission to refer to the relevant studies.
Costs related to the activities	Labour for operational unit per dispute (11.5 days): € 6 737 Labour for legal unit per dispute (4.25 days): € 2 490 **Total costs related to data-sharing disputes: € 9 226**
Years that costs will be allocated	**N:** evaluation phase

3.3 Costs related to horizontal activities

The costs related to horizontal activities provided by ECHA are given in the tables below. Costs are in €. The number of FTE used for the calculating the staff costs are given in the last column.

It should be noted that these horizontal activities belong to the core of the work the Biocides department at ECHA as set out in Regulation (EU) No. 528/2012. They are either activities supporting the work for handling applications made under Annex I, II and III, e.g. organising the Biocidal Products Committee, submission management and related IT tools, or activities which were clearly given to ECHA under the Regulation such as assistance to MSCAs on technical guidance or risks related to human health, animal health or the environment (Chapter XVI of the BPR).

Table 3-21 Costs related to the organisation of meetings, committees and working groups

Activity		Cost s	FTE
ME01 - Costs for Biocidal Products Committee and working groups for the preparation of up to 60-65 opinions per year[13] (to be doubled if the number of opinions goes beyond 90 every year)			
	Staff costs TA	€ 824 798	**6.4**
	Other: Related expenses	€ 100 000	
	Total cost	**€ 924 794**	
ME02 - Costs for Secretariat for the Coordination group			
	Staff costs TA	€ 167 536	**1.18**
	Total cost per dossier	€ **167 536**	
ME03 - Costs for Biocidal Products Committee and working groups for the preparation of of opinions in excess of 60-65 opinions per year (max. 80-90) (to be set to zero if the number of opinions exceeds 90 every year)			
	Staff costs TA	€ 289 957	**2.05**
	Other: Related expenses (organisation of additional meetings)	€ 100 000	
	Total cost r	€ **389 957**	

Table 3-22 Costs related to Communication, Helpdesk and guidance

Activity		Costs	FTE
HD01 - Costs for communication activities per year			
	Staff costs TA	€167 536	**1.18**
	Other: Related expenses	€ 108 800	
	Total cost per dossier	€ **276 336**	
HD02 - Costs for Helpdesk and HelpNet per year			
	Staff costs TA	€ 322 185	**2.27**
	Total cost per dossier	€ **322 185**	
DI01 - Costs for dissemination; the establishment and maintenance of databases with information on active substances and biocidal products and notification of decision taken by ECHA			
	Staff costs TA	€ 206.198	**1.18**
	Staff costs CA	€ 86 590	
	Total cost per dossier	€ **292.788**	

Table 3-23 Costs related to submission management

Activity	Costs	FTE
Up to 3 000 submissions: 1.5 FTE is needed; 0.5 FTE should be added for each further 1 500 submissions		

[13] When the number of opinions increase to over 90 to 130 per year, this budget item can be doublecounted.

	Staff costs TA	€ 257 748	**1.36**
	Total cost	€ **257 748**	

Table 3-24 Costs related to the specification of formats and software packages for the submission of information to the Agency

Activity		Costs	FTE
Management of submissions and support for applicants			
	Staff costs TA	**€ 257 748**	
	Other: FTE for dissemination		**2**
	Total cost:	**€ 257 748**	
Development of biocides IT tools for the submission of information to the Agency (R4BP, SPC Editor) - including also in parallel the maintenance work and the support to users (foreseen until 2018)			
	Staff costs TA	€ 1 237 190	**8.73**
	Other: Outsourcing costs	€ 1 000 000	
	Total cost	€ **2 237 190**	
Maintenance of biocides IT tools for the submission of information to the Agency (R4BP 3, SPC Editor). This includes also support to users (this task is mutually exclusive with the task above. Supposed starting date is 2019)			
	Staff costs TA	€ 618 595	**4.36**
	Other: Outsourcing costs	€ 400 000	
	Total cost	€ **1 018 595**	
Outsourced IT management services			
	Other: Management of Biocide services	€ 192 000	
	Total cost	€ **192 000**	
Contribution to IUCLID maintenance costs (driver: share of total number of IUCLID dossiers)			
	Other: Contribution to IUCLID maintenance costs	€ 20 000	
	Overheads assigned		
	Total cost	€ **20 000**	
Users training and SON (security officers network) meetings			
	Other: User training meetings	€ 60 000	
	Total cost	€ **60 000**	

Table 3-25 Costs related to the assistance to the Commission and the Member States

Activity		Costs	FTE
At the request of the EC or MSCA, any questions related to technical guidance or risks to human health, animal health or the environment			
	Staff costs TA	€ 16 988	**0.13**
	Staff costs legal	659	
	Total cost	€ **17 647**	
Providing support and assistance to MS with regard to confidentiality claims to be assessed by them (art. 66(4) of the BPR)			
	Staff costs TA	€ 51.550	**0.40**
	Total cost	**€ 51.550**	
Development of biocides functionalities for the Portal Dashboard to support national enforcement authorities (only in 2017)			
	Staff costs TA	€ 386 622	**2.73**

This is yet to be decided upon	Other: Outsourcing costs	€ 270 000	
	Total cost	€ **656 622**	
Maintenance of biocides functionalities for the Portal DashBoard to support national enforcement authorities			
Only becomes relevant after the development phase	Staff costs TA	€ 57 993	**0.41**
	Other: Outsourcing costs	€ 40 000	
	Total cost	€ **97 993**	

Table 3-26 Costs of the management of Biocides activities

Activity		Costs	FTE
Management of the Biocides assessment unit			
	Staff costs TA	€ 360 847	**2.55**
	Total cost	€ **360 847**	
Costs related to the development and maintenance of IT tools supporting the internal ECHA biocides processes			
	Other: ECM tools for biocides	€ 160 000	
	Total cost	€ **160 000**	

Table 3-27 Costs related to providing technical and scientific guidance and tools for the application of this Regulation by the Commission and Member States' CAs and providing support to national helpdesks

Activity		Costs	FTE
Costs for the development of BPR guidance documents per year			
	Staff costs TA	€ 141 761	**1.00**
	Other: Related expenses	€ 22 400	
	Total cost	€ **164 161**	
Specific outsourced scientific support to MS			
	Staff costs TA	€ 90 212	**0.64**
	Other: Outsourcing costs	€ 100 000	
	Total cost	€ **190 212**	
Development of specific IT tool for scientific purposes (EUSES) (only in 2017)			
This is a one off activity on which it still has to be decided.	Staff costs TA	€ 515 496	**0.91**
	Other: Outsourcing costs	€ 450 000	
	Total cost	€ 965 496	
Maintenance of specific IT tool for scientific purposes (EUSES) (from 2018 onwards)			
Only relevant after the development phase	Staff costs TA	€ 167 536	**0.32**
	Other: Outsourcing (spread over 2018 and 2019)	€ 20 000	
	Total cost	€ **187 536**	

Table 3-28 Other biocides expenses

Activity		Costs	FTE
Costs related to legal officers in support of other activities than those specifically identified above (e.g. support to Communication, Helpdesk, IT development, BPC, Coordination Group, access to documents requests, dissemination			
	Staff costs TA	€ 128 874	
	Staff costs legal	€ 117 158	**0.91**
	Total cost	**€ 246 032**	
Costs for support staff			
	Staff costs CA	**€** 519 540	**5.45**
	Total cost	**€ 519 540**	

Table 3-29 Contribution to ECHA's general costs

Activity		Costs
Contribution to ECHA general costs (excl. IT costs)		
	Other: Contribution according to the drivers (staff and surface of office space)	**€** 550 000
	Total cost	**€ 550 000**
Contribution to ECHA IT tools		
	Other: Contribution according to the drivers (staff and surface of office space)	**€** 450 000
	Total cost	**€ 450 000**

3.4 Comparing ECHA's costs and fees

Note: The costs of these activities as presented here do not include the direct costs they generate through the organization of the BPC, nor the overheads.

In the table below an overview is given of the costs for every activity covered by a fee. It indicates what the cost based fee should look like if 20% of the real costs are added to cover overheads and another 20% of the real costs are added as horizontal costs.

Table 3-30. Overview of real costs of each activity covered by fees and the current fee level

Cost heading	Real cost	Overheads assigned	Horizontal costs assigned	Total	Current fee level
A. Costs from activties under Annex I (active substances) in EUR					
Approval of an active substance; Article 7(2)					
Fee for the first product-type	20.840	4.168	4.168	29.175	120.000
Additional fee per additional product-type	17.691	3.538	3.538	24.767	40.000
Additional fee per producttype (for both the first product type and any additional product type) if candidate for substitution	4.101	820	820	5.741	20.000
Fee for the amendment of an approval, other than the addition of a product type.	20.620	4.124	4.124	28.868	20.000
Renewal of an approval; Article 13(3)					
Fee for the first product type	11.745	2.349	2.349	16.443	15.000
Additional fee per additional product type	11.599	2.320	2.320	16.238	1.500
Additional fee for the first product type for which renewal is sought in case a full evaluation is found necessary	6.092	1.218	1.218	8.529	25.000
Additional fee per additional product type in case a full evaluation is found necessary	6.092	1.218	1.218	8.529	2.500
Additional fee per product-type (for both the first product type and any additional product type) if candidate for substitution	4.101	820	820	5.741	20.000
Inclusion in Annex I of an active substance; Article 28					
Fee for the first inclusion in Annex I	20.840	4.168	4.168	29.175	10.000
Fee for the amendment of an inclusion in Annex I	12.331	2.466	2.466	17.263	2.000
B. Costs from activities under Annex II (biocidal products) in EUR					
Pre-submission for consultation for Union Authorisation					
Pre-submission for consultation for Union Authorisation	4.174	835	835	5.843	0
Granting of Union authorisation, single product; Article 43(2)					

Cost heading	Real cost	Overheads assigned	Horizontal costs assigned	Total	Current fee level
Fee per product not identical with (one of) the representative product(s) assessed for the purpose of the substance approval	24.457	4.891	4.891	34.239	80.000
Fee per product identical with (one of) the representative product(s) assessed for the purpose of the substance approval	24.237	4.847	4.847	33.932	40.000
Additional fee per product when comparative assessment is required	4.686	937	937	6.561	40.000
Additional fee per product when the requested authorisation is provisional	5.858	1.172	1.172	8.201	10.000
Granting of UA, BP family; Article 43(2)					
Fee per family	33.244	6.649	6.649	46.541	150.000
Additional fee per family when comparative assessment is required	7.029	1.406	1.406	9.841	60.000
Additional fee per family when the requested authorisation is provisional	4.101	820	820	5.741	15.000
Notification to the Agency of an additional product in a family; Article 17(6)					
Fee per additional product	732	146	146	1.025	2.000
Union authorisation of a same biocidal product; Article 17(7)					
Fee per product constituting a ‘same product’ specifying a procedure for the authorisation of same biocidal products	4.247	849	849	5.946	2.000
Union authorisation of a same biocidal product family; Article 17(7)					
UA10bis - Staff needed per product constituting a ‘same product’ specifying a procedure for the authorisation of same biocidal product family	7.249	1.450	1.450	10.149	2.000
Recommendation on the classification of a change; Article 50(2)					
Fee per request	7.469	1.494	1.494	10.456	2.000
Major change of an authorised product or product family; Article 50(2)					
Fee per application per BP	20.283	4.057	4.057	28.396	2.000
Fee per application per BPF	24.969	4.994	4.994	34.957	2.000
Minor change of an authorised product or family; Article 50(2)					

Cost heading	Real cost	Overheads assigned	Horizontal costs assigned	Total	Current fee level
Fee per application per BP	13.327	2.665	2.665	18.657	15.000
Fee per application per BPF	21.528	4.306	4.306	30.139	15.000
Admin. change of auth. product or family; Article 50(2)					
Fee per notification	3.661	732	732	5.126	2.000
Renewal of Union authorisation, single product; Article 45(3)					
Fee per product	13.839	2.768	2.768	19.375	5.000
Additional fee per product in case a full evaluation is found necessary	10.691	2.138	2.138	14.967	15.000
Additional fee per product when comparative assessment is required	4.686	937	937	6.561	40.000
Renewal of Union authorisation, biocidal product family; Article 45(3)					
Fee per product family	17.427	3.485	3.485	24.398	7.500
Additional fee per product family in case a full evaluation is found necessary	14.791	2.958	2.958	20.708	22.500
Additional fee per product family when comparative assessment is required	7.029	1.406	1.406	9.841	60.000
C. Activities under Annex III (other fees) in EUR					
Technical equivalence; Article 54(3)					
Fee, when difference between the AS sources is limited to a change in manufacturing location, and application is based solely on analytical data	5.126	1.025	1.025	7.176	5.000
Fee, when difference between the AS sources goes beyond a change in the manufacturing location, and application is based solely on analytical data	5.126	1.025	1.025	7.176	20.000
Fee when previous conditions are not met	14.645	2.929	2.929	20.503	40.000
Annual fee for BP auth. by the Union; Article 80(1)(a)					
Fee per Union authorisation of a BP	146	29	29	205	10.000
Fee per Union authorisation of a BP family	146	29	29	205	20.000
MR Submission fee; Article 80(1)(a)					

Cost heading	Real cost	Overheads assigned	Horizontal costs assigned	Total	Current fee level
Fee per product or product family per Member State where mutual recognition is sought	146	29	29	205	700
Renewal of MR	0	0	0	0	0
Appeal; Article 77(1)					
Fee per appeal	76.299	15.260	15.260	106.819	2.500
Litigation in court	27.532	5.506	5.506	38.545	0
Submission for inclusion in the list; Article 95					
Fee per submission of a letter of access to a dossier already found complete by the Agency or an eCA	3.332	666	666	4.664	2.000
Fee per submission of a letter of access to part of a dossier already found complete by the Agency or an eCA, together with complementary data	6.480	1.296	1.296	9.072	20.000
Fee per submission of a new dossier	6.480	1.296	1.296	9.072	40.000
Requests under Article 66(4) submitted to the Agency					
Fee per item for which confidentiality is requested	403	81	81	564	1.000

4 ECHA's Biocides revenues: estimates of the number of applications to Union Authorisation

This chapter provides the estimates of the number of Union Authorisations used in the simulations. The section 4.1 presents a review of the key drivers for ECHA's Biocides revenues. The hypothesis retained for the estimates of the Union Authorisation are presented in section 4.2. The estimates are provided in sections 4.3 for the year 2016, 4.4 for the year 2017 and 4.5 for the years 2018-2020. A summary of the estimates is provided in section 4.6.

4.1 Key drivers for ECHA's Biocides revenues

The ECHA's Biocides revenues depend to a large extent on the number of applications from the Biocide industry to Union Authorisation. This section provides a summary of the key drivers influencing the number of applications. It builds on the findings of a market analysis that include a description of the biocide industry and the results of a survey implemented in December 2015.

4.1.1 Overview of the market

The planning of the Review Programme forms the basis for the estimations on the number of Biocidal Products that needs to seek authorisation under the BPR due to the approval of their active substance participating in the Review Programme.

The updated planning of the Review Programme contains the dates of approval and the deadlines for submission of the applications for product authorisations if the applicant wants to keep its BP on the market. It is expected that the number of submissions for product authorisation will spike right before the deadlines. Currently, this planning gives a sound projection of active substance approval until the end of 2018.

The number of "existing Biocidal Products" going for product authorisation are based on two sources of information. For active substances under Product Types not yet approved under the Review Programme, data from National Competent Authorities experienced in product authorisations (i.e. Belgium, Netherlands, UK) is used to estimate an average number of Biocidal Products per active substance for each Product Type. The average number of products per active substance for a certain product type renders a good idea of the magnitude of the market.

Averages have been calculated on number of Biocidal Products per AS for each PT based upon the data gained from the Competent Authorities of 19 Member States[14]. These averages can be found in table 4-1.

[14] It is important to realize the limitations of these data. Only a very limited amount of the MSCAs have a substantial database of all BPs on their market. Furthermore, these databases are not designed to be used in this manner. However, within these limits and the non-existence of one single biocides market (it is rather segmented) this data is a very valuable indication of the magnitude and structure of this industry.

Table 4-1 The average number of authorised Biocidal Products per active substance per Product Type[15]

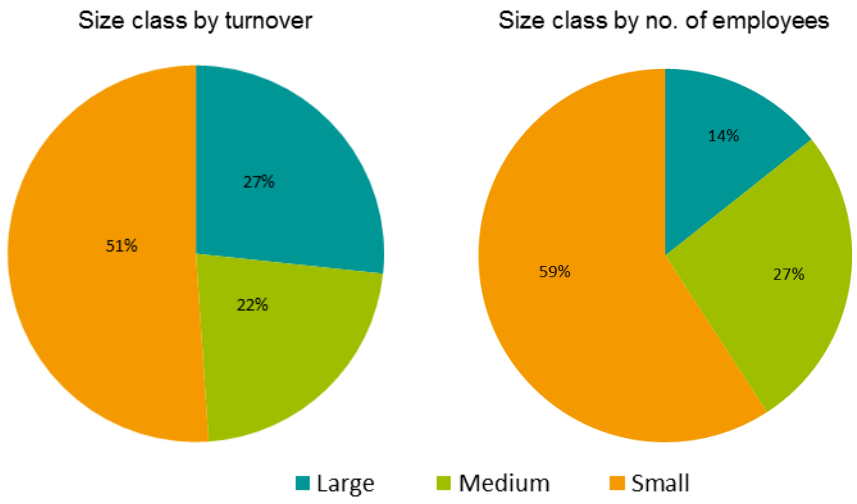
PT	BE	UK	NL	AT	CZ	EE	LV	MT	SI	SK	HR	HU	DE	ES	SE	FI	PT	CY	FR	EU AVERAGE
1	7,09		1,72			2,01	2,17	1,20	2,84		1,19		8,33	17,96				1,27	12,18	5,27
2	15,57		2,36		1,00	1,78	2,17	1,27	2,95		1,18	8,00	149,48	4,63	5,00			1,50	33,65	16,47
3	7,43		1,91		1,00	2,81	1,64	1,71	2,08		1,10	1,00	25,20	12,06			2,66	1,21	10,80	5,19
4	21,66		2,24		1,00	2,03	2,18	1,00	2,45		1,13	1,00	36,83				3,86	1,05	18,17	7,28
5	18,33		2,82		1,00	1,00	1,64	1,00	2,14		1,14		90,75				1,00		10,77	11,96
6	6,78		1,22			1,11	1,31		1,43		1,08	2,00	7,11					1,00	4,15	2,72
7	2,67		1,00			1,33	1,45		1,41		1,00		34,10					1,00	3,61	5,29
8	6,59	4,61	1,34	3,21		0,88	1,48	2,00	6,51	7,80	1,09	5,25	37,45	3,19	1,32		1,21	1,20	8,57	5,51
9	4,75		1,11			1,17	1,38		1,27		1,00		26,00		1,00				16,69	6,04
10	15,39		3,70			1,00	1,69		1,58		1,07							1,00	19,56	5,62
11	12,48		3,04			1,25	1,71	1,00	2,03		1,05		11,18	1,25				1,00	7,37	3,94
12	9,28		2,59			1,00	1,18	1,00	2,11		1,00		45,73	1,00	5,17				8,73	7,16
13	5,25		1,37				1,27		1,52		1,00		35,10						3,23	6,96
14		3,00	3,33		6,50		2,40	4,00	8,00	5,25	3,00	8,75	107,73						58,64	19,15
15			1,00						1,00				6,00							2,67
16													0,00							0,00
17													0,00							0,00
18	4,96	6,05	2,20	2,43	1,00	1,28	1,92	1,79	2,77	2,50	3,00	3,50	65,96	5,73	2,42	3,74	1,50	1,28	17,90	6,94
19	12,78	6,39	0,00	1,25		2,62	2,23	1,00	4,33	4,00	1,41	9,67	107,80	16,25	7,50	7,40	3,00	1,20	34,32	12,40
20													0,00							0,00
21	1,00	6,25	1,34			2,11	4,33	3,00	2,19		1,38		104,43		6,43	1,87		1,00	11,47	11,29

[15] Some MS Competent Authorities have not been experienced with the authorisation of BIocidal Products in the past. Due to the BPR, now they are obliged to authorise all the Biocidal Products on their market. They mostly follow the Review Programme for this, which explains why some only have authorization of PT 04, 08,14 and 18.

The market analysis is conducted by using the data from National Competent Authorities databases. In these lists, all companies holding National authorisations are represented. These lists do not have the same level of comprehensiveness for each Member States but they give a good overview of the biocidal sector. By use of the Amadeus database, estimations are made on the size and the composition of the sector, i.e. the percentage of SMEs, the average turnover, no. of people employed, etc.

The market analysis provides a well-documented idea on the average number of products per company in a certain size class and support the estimates on “existing Biocidal Products” for which authorisation needs to be sought related to the Review Programme and on “new Biocidal Products” to be brought on the market.

Figure 4-1 **The percentage of SMEs in the EU market (data from Amadeus for companies having an authorised Biocidal Product with any of the 15 MS CA)**



4.1.2 Industry survey and stakeholders consultation

Detailed results from our survey are provided in annex 1: this section provides a summary of the key findings, including a comparison with the results from the study “A.I.S.E. & EBPF survey on the BPR Impact on Biocidal Products and Innovation” published in December 2015

Regarding the intention of the industry for the number of applications for Union Authorisation, our survey indicates in total 140 applications between the year 2016 and the year 2020. In the survey implemented by A.I.S.E./EBPF, the total number of dossier foreseen to be sent to ECHA is 360, including 209 individual BP and 151 BP Families (44% of the total number). The main PT are the PT 2 (25 in our survey, 79 in A.I.S.E./EBPF survey) followed by PT4 (25 in our survey, 35 in A.I.S.E./EBPF survey).

When asked the question of choosing either National Authorisation (NA) or Union Authorisation (UA) the companies generally favour NA when only a limited number of markets are served. From the survey results, the threshold for choosing UA is sales in more than on average 10 EU markets.

There is also strong agreement among the respondents that the outcome of a UA compared to NA/MR is more uncertain. This uncertainty highlight the importance of the experience that will be

gained by the industry in the coming two years: in case of negative experience with the Union Authorisation procedure, the number of applications could be significantly lower that stated in the survey.

The Family Procedure is recognized by some respondents as a driver for choosing UA in comparison to NA/MR although some of the respondents claimed that in some case, the Family Procedure could remain more costly than the NA/MR procedures for all products.

The main findings from the interviews with regard to the costs of bringing BP and AS to the EU market, and related authorization routes, can be summarized as follows:

- Development of new BP takes approximately 2 to 3 years. Approximately after one year a company starts preparing the authorization dossier;
- Cost associated with the development of BP were estimated in the range from 200 thousand EUR to 2 million EUR, depending on the markets served, type of the products and AS used;
- Preparation of the authorization dossier is intensive for human resources and requires both researches and administrative staff. Bigger companies employ full time employees that take care solely of the authorization;
- Companies use the help of external consultancies to support their authorization process;
- Opportunity costs are not very relevant since the companies are very clear with the choice of the their authorization route depending on the number of markets they serve. Small companies will always go for national authorization and can consider MR in other markets if they decide to expand to other markets. Larger companies active in several MS will opt for UA since management of various MR in the same time can prove very complicated;
- Authorization costs pose a significant part of the total costs of placing a product at the market and can be up to 50% of the total costs;
- Large companies face high costs due to the one-time payment of BP authorization fees and large portfolios of BP that must be authorized in a short time. This pressure may result in some BPs to be dropped from the EU market.

Finally, all companies from the survey stated that the fees were high or too high. The costs for authorisation compared to development costs for BPs are considered too high. Companies show some discouragement when it comes to the balance between the fee level and the work carried out by ECHA. The survey showed that some companies felt there was no transparency of the work carried out for the registration fee, as most of the work was carried out by national authorities. One respondent claimed that there should be a balance between the workload coming with a registration, so a simple registration should be less costly compared to a more complicated registration. The United Kingdom was mentioned here as an example of a good system for a differentiated approach to the fee level. Also the Netherlands was mentioned as a country with transparency of the work carried out and the payment.

4.2 Estimates of the number of applications for Union Authorisation

4.2.1 Hypothesis retained for the estimates

The estimates of number of submissions for UA have been made according to the following principles

- The list of AS under the Review Programme which imply a deadline for product authorisation in the respective years and the corresponding PTs have been identified (after 2017, these deadlines are subject to the progress of the Review Programme);
- For the reviewed AS, information on the outcome of the RP has been reported. AS meeting the exclusion criteria are not eligible for UA and have thus been excluded from further analysis. From the consultation with the industry associations, it has become clear that when an AS is a candidate of substitution, the industry will most likely prefer National Authorisation and Mutual Recognition or might discontinue the production of this BP. When the first assessments are made on BPs with AS being candidates for substation at Union level, companies will base future decisions on the outcome of this process;
- The number of BPs containing the AS currently on the market as reported by data provided by the Member States Competent Authorities (MSCAs) has been calculated. These numbers render a good impression of the magnitude of the market, yet are non-conclusive due to the limitations of the data[16]. They are an underestimate due to the fact that the current period is still a transition period between the BPD and the BPR and many MSCAs do not have a complete overview of all the BPs on their market. Some of the databases of MSCAs were not able to render data in a format which is appropriate for this type of analysis, so they were excluded as well. All information given in the tables on the following pages indicates which data has been used;
- The intention of industry to opt for UA for their products per PT in each year is reported based on our survey results and/or the results from the AISE/EBPF survey;
- Both industry and stakeholder associations have indicated that when the deadline for the authorisation of a product containing a certain active substance, precedes the date of eligibility for UA, the willingness to choose for UA is very low. The long duration of the UA process combined with uncertainty on the outcome are the main underlying drivers of this decision.

Industry and stakeholder associations have emphasised that the first UA processes will have a significant effect on the choice for an authorisation route. This finding forms the basis for the three scenarios:

- The baseline scenario takes into account that UA processes started in 2015 are generally on track, yet some minor organisational barriers were encountered. Companies had a good experience, but remain hesitant to fully go for UA in the first years and rather wait until the learning phase has passed;
- The conservative/pessimistic scenario takes the hypothesis that the UA processes started in 2015 are delayed or companies have had a poor experience and express doubts in following this authorisation route in the future;
- The optimistic scenario starts from the assumption that UA processes are going well and are on track for a timely decision. No major issues have been encountered and industry has increasingly chosen to opt for UA instead for NA+MR. As more companies choose for UA, other players in the same market feel inclined to go for UA as well in order to remain competitive.

Based on the principles described above, the baseline scenario makes use of recent trends observed in the surveys and of information provided by ECHA. The second scenario is more pessimistic as it is based upon bad experience and can go below current estimates from 2018 onwards.

[16] It is important to realize the limitations of these data. Only a very limited amount of the MSCAs have a substantial database of all BPs on their market. Furthermore, these databases are not designed to be used in this manner. However, within these limits and the non-existence of one single biocides market (it is rather segmented) this data is a very valuable indication of the magnitude and structure of this industry.

4.2.2 *Estimates per year*

The following tables summarise the estimates for the number of applications for Union Authorisations. The details of the reasoning is provided in Annex 2 (one table for each year).

Table 4-2 Estimates of the number of applications for UA in 2016

	Pessimistic	Baseline	Optimistic
Single product UA	6	10	11
Biocidal Product Family UA	10	10	12
Total	16	20	23

Table 4-3 Estimates of the number of applications for UA in 2017

	Pessimistic	Baseline	Optimistic
Single product UA	13	16	27
Biocidal Product Family UA	14	19	27
Total	27	35	54

Table 4-4 Estimates of the number of applications for UA in 2018

	Pessimistic	Baseline	Optimistic
Single product UA	4	11	17
Biocidal Product Family UA	11	19	39
Total	15	30	56

Table 4-5 Estimates of the number of applications for UA in 2019

	Pessimistic	Baseline	Optimistic
Single product UA	7	18	40
Biocidal Product Family UA	8	21	41
Total	15	39	81

Table 4-6 Estimates of the number of applications for UA in 2020

	Pessimistic	Baseline	Optimistic
Single product UA	14	31	47
Biocidal Product Family UA	11	25	49
Total	25	56	96

4.2.3 *Summary: estimates for the entire period*

The table below provides a synthesis of the number of applications for each year and for each scenario. The total number of applications in the baseline scenario is 180. It ranges from 98 in the pessimistic scenario to 310 in the optimistic scenario. These numbers should be compared with the intention declared in our survey (140 applications) and in the AISE/EBPF survey (360 applications but I the report indicates that it is over-estimated).

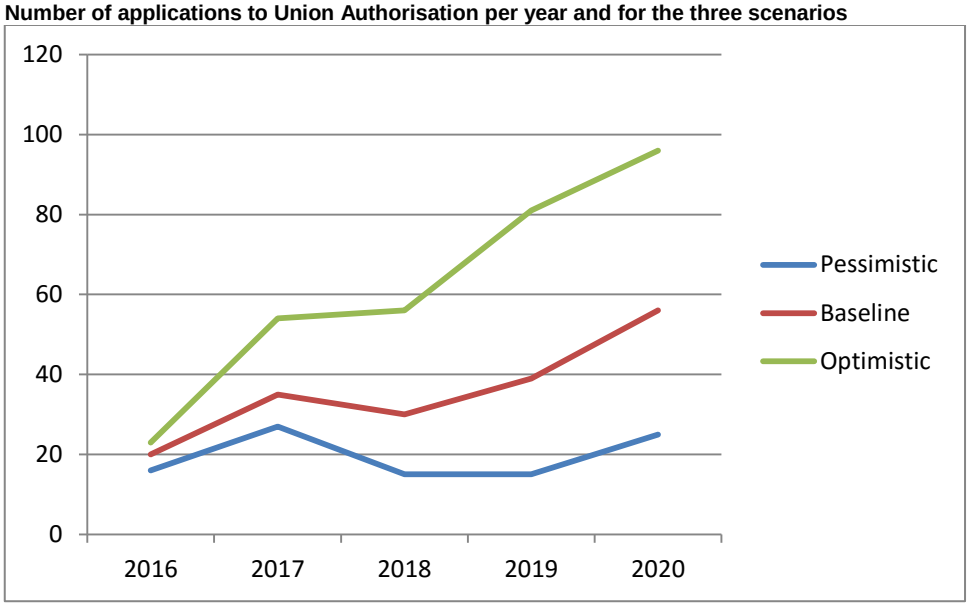
Table 4-7 Summary of the estimates of the number of applications for Union Authorisations for the period 2016-2020

	2016	2017	2018	2019	2020	Total
Pessimistic	16	27	15	15	25	98
Baseline	20	35	30	39	56	180

Optimistic	23	54	56	81	96	310

The figure 4.2 illustrates the evolution of the number of applications between 2016 and 2020.

Figure 4-2 **Number of applications to Union Authorisation per year and for the three scenarios**



It shows an important increase in 2017 compared to 2016 (+ 11 applications in the pessimistic scenario, + 15 in the baseline scenario and + 31 in the optimistic scenario). For 2018, there is a decline of the number of applications in the pessimistic scenario (reflecting bad experience from the industry in the years 2015, 2016 and 2017) and a stability in the optimistic scenario. The differences between the scenario amplifies in the following years as the number of applications increase from 56 in 2018 to 81 in 2019 for the optimistic scenario and remain stable at 15 applications for the pessimistic scenario.

These evolutions reflect the hypothesis taken for the analysis: the pessimistic scenario takes the hypothesis that the UA processes started in 2015 are delayed or companies have had a poor experience and express doubts in following this authorisation route in the future while in the optimistic scenario, the UA processes are going well with no major issues and as more companies choose for UA, other players in the same market feel inclined to go for UA as well in order to remain competitive.

5 Results of the simulations

This chapter provides the results of simulations of ECHA's budget. The simulations aim at assessing the impact of the number of applications on the costs and revenues of the agency's BPR activities. The simulations have been prepared with the help of the Financing Model according to the three different scenarios described in chapter 4.

The three scenario described in chapter 4 have been tested in three different policy options.

- The first policy option is a status quo. In this option, the estimates of the number of applications as described in chapter 4 are utilised to run the financial model. In this policy option, there is no change in the current Commission Implementing Regulation No 564/2013;
- The second simulation considers the impact of a change in the fee level. It consider five different options: change of the fees in annex I and II (option B1) , in annex III (option B2) , in annex I,II and II (option B3), changes in the annual fee (option B4) and changing fee levels to make Union Authorisation more attractive. Each option estimates the impact on the EU subsidy to ECHA of an increase of the fee by 15 and 20%, a decrease by 10% and setting the fees to a cost-based level. Option B5 considers the impacts on the increase in applications and the decrease of number of MR requests.
- In the third simulation a change in the payment conditions is tested. The possibility to pay the fees for Union Authorisation of Biocidal product and for Active substance Approval in two and three instalments is introduced.

5.1 Results of the simulations for the policy option A "status quo"

In this policy option, the costs and revenue for ECHA are calculated for each year and for each scenario described in chapter 4. The Financial Model developed in this study is used with the hypothesis described in chapter 3 for calculating the costs and in chapter 4 for estimating the number of applications to ECHA. The revenue is calculated by taking into account the level of the fee as described in the Commission Implementing Regulation No 564/2013. The results are presented in three sections: costs and revenues (5.1.1), EU subsidy (5.1.2) and number of staff (5.1.3).

5.1.1 Costs and revenues in the three scenarios

The results of the simulations are provided in the table below. The tables provide for each year the estimates of the expenditures (costs related to the applications, horizontal costs, fixed costs and total costs), estimates of the revenues (number of application multiplied by the fee value) and the EU subsidy required to balance the annual budget (differences between the costs and the revenues).

For the baseline scenario, the costs varies between € 11 and 12 million. The revenue from the fee varies between € 7 and 11 million. The high revenue for 2018 (€ 11 million) is mainly explained by the high number of applications for active substance approval expected by ECHA (38 in 2018).

Table 5-1 Summary of costs and revenues for ECHA with the baseline scenario (in million €)

	2017	2018	2019	2020
Costs related to applications	*3,71*	*4*	*4,12*	*4,39*
Horizontal costs	*6,69*	*5,94*	*5,89*	*6,47*
Fixed costs	*1*	*1*	*1,13*	*1,13*
Total costs per year	*11.40*	*10,93*	*11,14*	*12*
Revenues per year (from fees)	*7,34*	*11*	*8,39*	*10,12*

Difference Costs -Revenues	*4,06*	*-0,06*	*2,75*	*1,88*

In the optimistic scenario, the costs gradually increase to reach € 12,92 million in 2020. From 2018 onward, the revenue is higher than the costs.

Table 5-2 **Summary of costs and revenues for ECHA with the optimistic scenario (in million €)**

	2017	2018	2019	2020
Costs related to applications	*3,76*	*4,17*	*4,79*	*5,31*
Horizontal costs	*6,69*	*5,94*	*5,89*	*6,47*
Fixed costs	*1*	*1*	*1,13*	*1,13*
Total costs per year	*11,44*	*11,11*	*11,82*	*12,92*
Revenues per year (from fees)	*9,31*	*14,70*	*13,065*	*15,39*
Difference Costs -Revenues	*2,13*	*-3,59*	*-1,25*	*-2,47*

For the pessimistic scenario, the costs vary between € 10,8 and 11,5 million. In this scenario, the difference between the costs and revenue remain substantial in 2019 and 2020 at more than € 5 million.

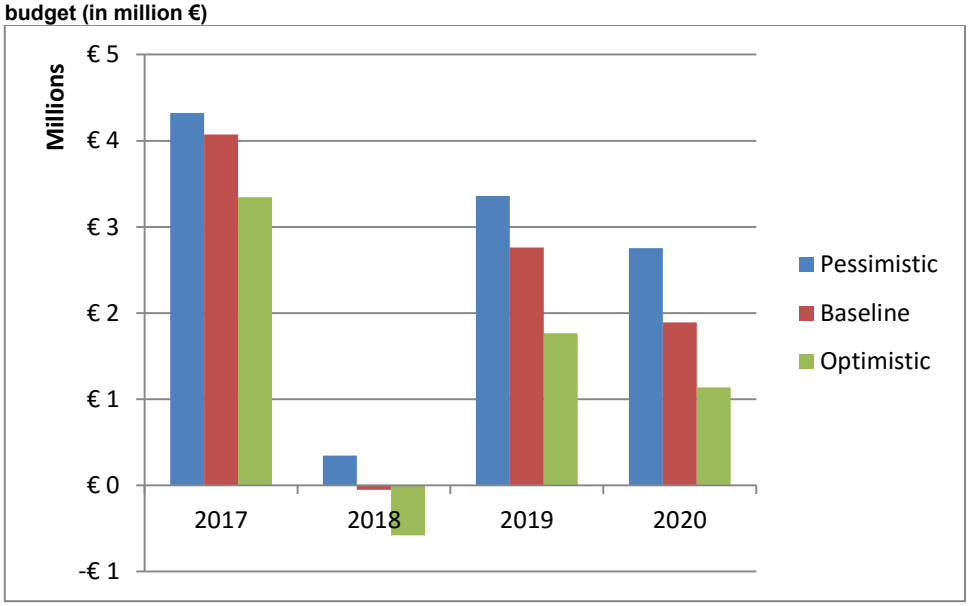
Table 5-3 **Summary of costs and revenues for ECHA with the pessimistic scenario (in million €)**

	2017	2018	2019	2020
Costs related to applications	*3,70*	*3,85*	*3,81*	*3,86*
Horizontal costs	*6,69*	*5,94*	*5,89*	*6,47*
Fixed costs	*1*	*1*	*1,13*	*1,13*
Total costs per year	*11,38*	*10,79*	*10,84*	*11,47*
Revenues per year (from fees)	*6,33*	*9,25*	*5,54*	*6,62*
Difference Costs -Revenues	*5,06*	*1,53*	*5,30*	*4,84*

5.1.2 EU subsidy

The figure below illustrates the EU subsidy required to balance the annual budget for each of the scenario. The need for a subsidy remains in the range of € 3 million in the baseline scenario (to the exception of 2018, as explained by the high number of application of active substance). It reaches € 5 million in the pessimistic scenario. In the optimistic scenario, there is no need for a EU subsidy from 2018.

Figure 5-1 **Annual contribution from the General budget of the EU (EU subsidy) required to balance the ECHA budget (in million €)**



5.1.3 *Number of staff*

Based on the financial Excel model, the number of staff required is estimated in the tables and in the figure below.

These numbers show that there is no significant variations between the three scenarios, except for the years 2019 and 2020 (respectively 8 and 12 additional FTE for the optimistic scenario compared to the pessimistic scenario).

Table 5-4 **No. of staff needed in the baseline scenario (in FTE)**

	2017			2018			2019			2020		
	TA	**CA**	**LE**	**TA**	**CA**	**LE**	**TA**	**CA**	**LE**	**TA**	**CA**	**LE**
Staff needed activities under Annex I, II and III	14	0	1	16	0	0	19	0	1	21	0	1
Staff for other applications (Review Programme and art. 95, Checks and opinions)	13	0	0	13	0	0	12	0	0	12	0	0
Staff for horizontal activities	29	7	1	31	7	0	31	7	1	35	7	1
Total staff per year	**57**	**7**	**2**	**60**	**7**	**0**	**61**	**7**	**3**	**67**	**7**	**3**

Note: LE means legal staff

Table 5-5 **No. of staff needed in the optimistic scenario (in FTE)**

	2017			2018			2019			2020		
	TA	CA	LE	TA	CA	LE	TA	CA	LE	TA	CA	LE
Staff needed activities under Annex I, II and III	5	0	1	18	0	0	24	0	1	28	0	1
Staff for other applications (Review Programme and art. 95, Checks and opinions)	13	0	0	13	0	0	12	0	0	12	0	0
Staff for horizontal activities	29	7	1	31	7	0	31	7	1	35	7	1
Total staff per year	**57**	**7**	**2**	**61**	**7**	**0**	**66**	**7**	**3**	**74**	**7**	**3**

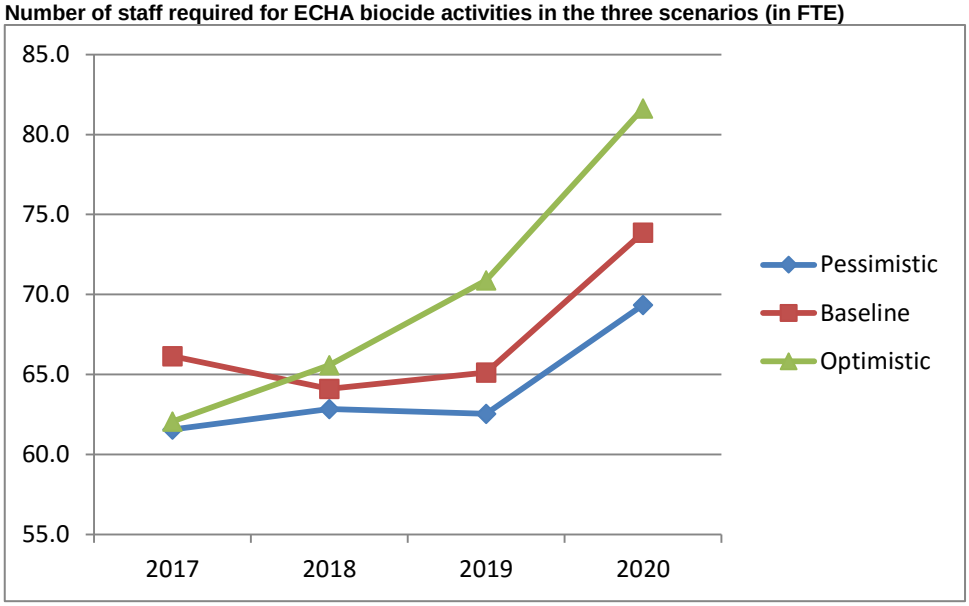
Note: LE means legal staff

Table 5-6 **No. of staff needed in the pessimistic scenario (in FTE)**

	2017			2018			2019			2020		
	TA	CA	LE	TA	CA	LE	TA	CA	LE	TA	CA	LE
Staff needed activities under Annex I, II and III	14	0	1	15	0	0	16	0	1	17	0	1
Staff for other applications (Review Programme and art. 95, Checks and opinions)	13	0	0	13	0	0	12	0	0	12	0	0
Staff for horizontal activities	29	7	1	31	7	0	31	7	1	35	7	1
Total staff per year	**57**	**7**	**2**	**59**	**7**	**0**	**59**	**7**	**3**	**63**	**7**	**2**

Note: LE means legal staff

Figure 5-2 **Number of staff required for ECHA biocide activities in the three scenarios (in FTE)**



5.2 Results for the policy option B: change in the fee level

Under this policy option, we consider a change in the fee levels in order for ECHA to have a balanced budget (i.e. in the Excel financial model, the EU subsidy in 2020 is zero or the costs of the Review Programme are covered). Four options have been considered:

- Increase of the fees in Annex I (Active Substance Approval) and in Annex II (Biocidal Product Authorisation);
- Increase of the fee in Annex III (other fees including the annual fee);
- A combination of the two (increase in Annex I, II and II);
- Only a change of the annual fee, maintaining all other fees at the current level combined with an increase of the MR fee.

In all possibilities the same baseline scenario has been used in order to fully grasp the effect this reduction has on the revenue side of ECHA's budget without the additional change in costs due to different numbers of applications.

All results are shown as the effect the hypothesis has on the EU subsidy, i.e. a reduction or an increase.

5.2.1 Results of the simulation

Option B1: change in fees under Annex I and II

In the first option, the fees under Annex I and II are subsequently increased by 15 and 20% and decreased by 10%.

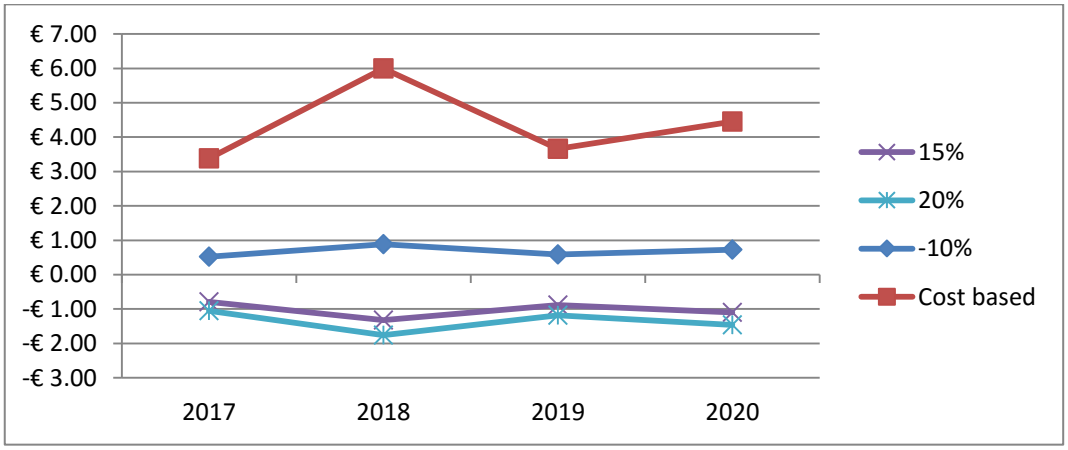
The table below indicates the results of the different possibilities.

Table 5-7. Variation in EU subsidy induced if Annex I & II fees are changed (difference between subsidy in case of higher or lower fees and subsidy in status quo, in million €)

	2017	2018	2019	2020
Status quo absolute level	4,07	-0,05	2,76	1,89
Reduction if fees increased by 15%	-0,79	-1,32	-0,88	-1,10
Reduction if fees increased by 20%	-1,05	-1,76	-1,18	-1,46
Increase if fees reduced by 10%	0,52	0,88	0,59	0,73
Setting fee to a cost based level[17]	3,38	6	3,66	4,45

The increase of the fees does not have a significant impact (remains under 1 million € decrease) for the EU subsidy until 2018 for all options. In order to have the EU subsidy only covering the Review Programme by 2020, an increase of 15% would be needed. However as indicated in Figure 5-3 below, even without an increase, a budget in balance is reached in 2018 and even with the increase the there will still be a need for an EU subsidy.

Figure 5-3. Reduction or increase of EU subsidy if fees under Annex I and II are changed (in million €)



Option B2: change in fees under Annex III

[17] The cost based fee level is based upon the costs inclined under each activity and includes a provision of 20% for overheads and 20% for horizontal costs

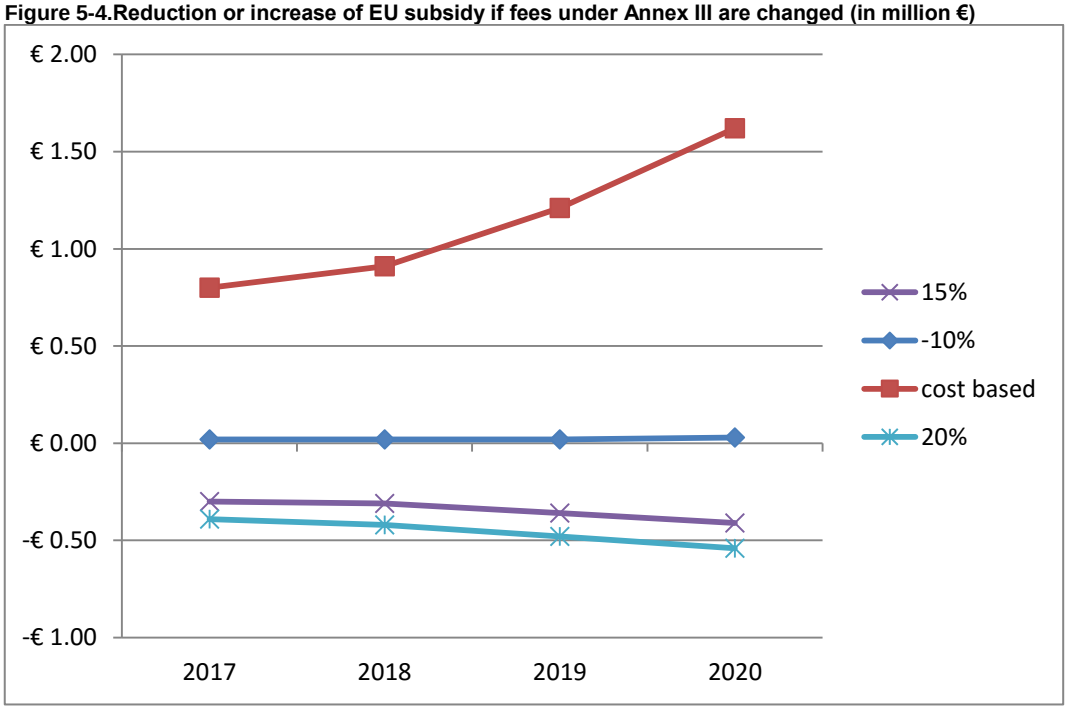
In the second option, the fees under annex III are increased by 15 and 20% or reduced by 10%. The table below indicates the results in terms of increase or decrease of the EU subsidy after implementation.

Table 5-8. Variation in EU subsidy induced if Annex III fees are changed (in million €)

	2017	2018	2019	2020
Status quo absolute level	4,07	-0,05	2,76	1,89
Reduction if fees increased by 15%	-0,30	-0,31	-0,36	-0,41
Reduction if fees increased by 20%	-0,39	-0,42	-0,48	-0,54
Increase if fees reduced by 10%	0,02	0,02	0,02	0,03
Setting fee to a cost based level[18]	0,80	0,91	1,21	1,62

An increase of the fees under Annex III does not have a significant impact (the reduction of the EU subsidy remains under 1 million €). The EU subsidy would still have to cover more than the Review Programme (except for in 2018), if only fees under Annex III are increased. A decrease would only imply an increase of the EU subsidy of maximum € 250 000.

Figure 5-4.Reduction or increase of EU subsidy if fees under Annex III are changed (in million €)



Option B3: change in fees under Annex I, II and III

In the third option, all the fees were increased by 15 and 20% and subsequently decreased by 10%. All the fees indicated in the previous paragraphs which did not cover the costs were set at levels in order to better cover the costs. Results are shown in the table below as the decrease or increase of the EU subsidy vis-à-vis the status quo scenario.

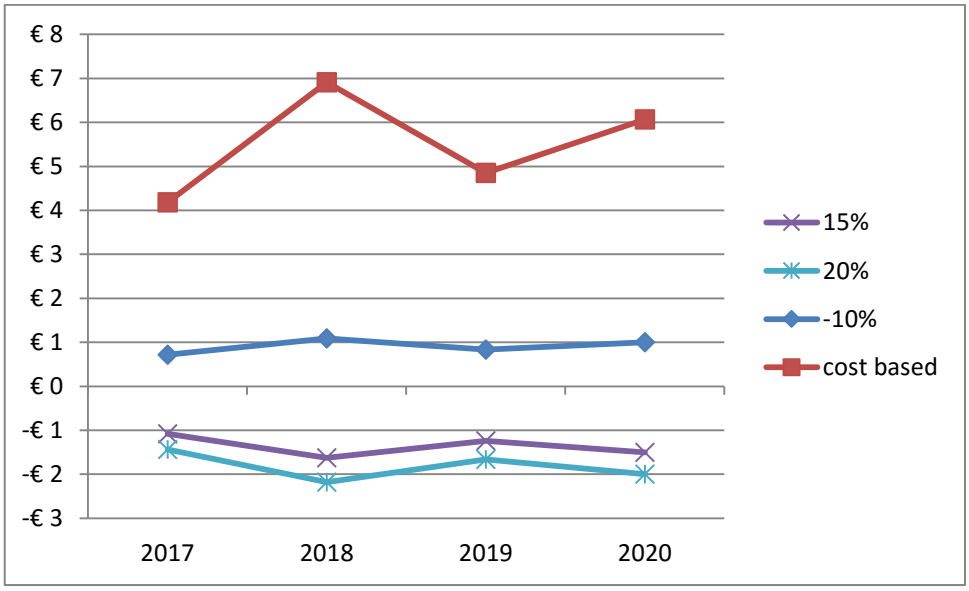
[18] The cost based fee level is based upon the costs inclined under each activity and includes a provision of 20% for overheads and 20% for horizontal costs

Table 5-9. Variation in EU subsidy induced if all fees are changed (in million €)

	2017	2018	2019	2020
Status quo absolute level	4,07	-0,05	2,76	1,89
Reduction if fees increased by 15%	-1,08	-1,63	-1,24	-1,50
Reduction if fees increased by 20%	-1,44	-2,18	-1,66	-2,00
Increase if fees reduced by 10%	0,72	1,09	0,83	1,00
Setting fee to a cost based level[19]	4,18	6,91	4,85	6,07

When all fees are increased by 15%, the EU subsidy can cover only the costs under the Review Programme in 2020. A reduction of all fees does imply a substantial increase of the EU subsidy compared to the status quo in all years. A balance will not be reached with a maximum increase of 20%.

Figure 5-5. Reduction or increase of EU subsidy if all fees are changed (in million €)



Option B4: change in the annual fee

In a final option, both the increase or decrease of only the annual fees for union authorised biocidal products and biocidal product families is tested. The table below shows that this will only have an impact from 2018 onwards, when the first union authorised products are on the market.

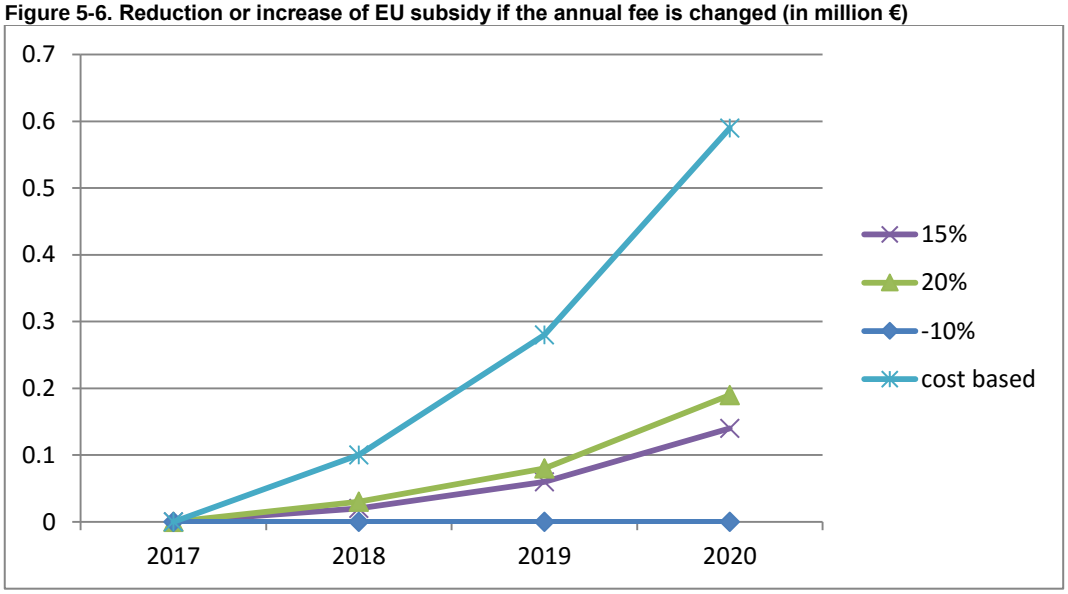
Table 5-10. Variation in EU subsidy induced if only annual fee is changed for the baseline scenario (in million €)

	2017	2018	2019	2020
Status quo absolute level	4,07	-0,05	2,76	1,89
Change in EU subsidy if reduced by 15%	0	0,02	0,06	0,14
Change in EU subsidy if reduced by 20%	0	0,03	0,08	0,19
Change in EU subsidy if increased by 10%	0	0	0	0
Change in EU subsidy if annual fee set to € 2.000 for BP and €10.000 for BPF	0	0,10	0,28	0,59

[19] The cost based fee level is based upon the costs inclined under each activity and includes a provision of 20% for overheads and 20% for horizontal costs

Both the table above and the figure below, show that neither an increase, nor a decrease has a significant impact on the EU subsidy. The highest increase of EU subsidy due to a 20% reduction on the current annual fee level will amount to around € 2,89 million.

Figure 5-6. Reduction or increase of EU subsidy if the annual fee is changed (in million €)



Option B5: Making Union Authorisation more attractive

Under this option, Union Authorisation is made more attractive. This will be done on the one hand, by implementing a fee for first national authorisation and on the other hand by increasing the fee for Mutual Recognition. It should be taken into account that this system of authorisations is not meant to compete with the system of national authorisation and mutual recognition. National competent authorities are still involved as evaluating Competent Authorities in the Union Authorisation.

By introducing an extra fee on first national authorisation the threshold of markets will become lower. However, it should be taken into account that by doing this, small companies targeting only one market will be faced with increased fees for the authorisation of their products. Therefore, it is proposed to only include a small fee for first national authorisation which can cover costs incurred by ECHA relating to the IT tools combined with a higher fee for Mutual Recognition for ECHA. The latter will be more effective in reducing the threshold of the number of markets a certain company is targeting for Union Authorisation. Currently, when looking at the national fees as they are currently implemented[20], the objective threshold lies at around 10 Member States before the costs related to the authorisation lie above that of the current ECHA fees. This excludes of course the management costs for companies of the coordination of these different Mutual Recognition applications.

We will test following option: an increase of the MR fee to € 1.000, first national authorisation fee of € 200.

In order to test the effect on UA, we will increase the number of applications for UA for both BP and BPF and decrease the number of MR fees.

Following assumptions are made[21] to increase the number of applications:

[20] Based upon CA-March15-Doc.7.2 – Report on the fees payable to Member States Competent Authorities pursuant to Article 80(2) of the Biocidal Product Regulation

[21] It should be noted that these are hypothetical assumptions, based upon the best information possible. The real numbers might differ as companies might choose to stop certain product lines due to these costs or might be more inclined to go for UA due to these changes.

- The increase of the first national authorisation fee to € 200 and the MR fee to € 1.000 will reduce the threshold by 2 MS.
- We assume that on average, one company makes 6 requests for MR. In the baseline scenario the number of requests for MR was 1.200, which implies that 200 unique BPs or BPFs were applied for.
- Although there might be exceptions to this rule, to simplify the simulation the assumption is that 49% of these unique applications come from medium or large companies[22] which are likely to target a number of countries around the threshold value of 10 MS.
- Assuming that not all companies might be as interested in going for UA, but keeping in mind the market structure, following assumptions is made:
    - 49% of the unique applications will be around the threshold value of 10 MS: 98 applications;
    - Of these 98 applications, 60% is assumed to prefer UA[23]: 58 applications remaining.
    - Of these 58, 60% is expected to apply for the BPF concept – 34 applications.
    - It is assumed that 81% will come from medium-sized companies (based upon the market structure), which implies 28 applications for BPF and 19 for BP.
    - It is assumed that 19% will come from large companies, implying 6 companies for BPF and 5 for BP.
- It is assumed that the increase of the level of the MR fee, will have also an impact on the number of products which will be applying for authorisation. In this simulation a further reduction of 10% was assumed. This implies that the remaining number of requests for MR is set at 900.

This implies the following change to the number of applications made in each year.

Table 5-11. Overview of number of applications if the MR fee and the annual fee change

Title of activity	2017	2018	2019	2020
Single product authorisation	50	45	52	65
BPF authorisation	43	43	45	49
MR applications	900	900	900	900
No. of first NA[24]	142	142	142	142

The result of this change has an impact on the revenue of ECHA on the one hand, and on the number of staff needed on the other hand. As you can see in Table 5-12, the impact on the EU subsidy is quite substantial. This is to be expected as the costs of MR are very low compared to the fee.

Table 5-12. Overview of the reduction of the EU subsidy needed if the MR fee is increased and the fee for first national authorisation implemented (in million €)

	2017	2018	2019	2020
Status quo absolute level	4,07	-0,05	2,76	1,89
Change in EU subsidy by increasing MR and fee for first authorisation	-5,86	-5,53	-3,97	-3,94

[22] Based upon the numbers of Figure 4-1

[23] Based upon own estimations coming from the findings of the surveys. Some companies are very critical towards Union Authorisation.

[24] Based upon the assumption of 200 unique applications, of which 58 went for UA due to the increase in MR fee.

In Table 5-13, it shows that this will however increase the number of staff needed due to the increase in the number of applications. There should be a good consideration on whether this is possible to implement taken into account the timeframe and the need for skilled staff.

Table 5-13. Overview of the impact of the MR fee change on the number of staff

	2017	2018	2019	2020
Status quo staff	**66**	**67**	**71**	**77**
Change in staff due to increased applications	67	69	84	90

To conclude, changing the level of the fee for Mutual Recognition and introducing a fee for first authorisation could have a positive impact on the number of applications for UA. However, two issues need to be taken into account. On the one hand, this might affect especially micro and small companies which are only present on one market and not interested in or well aware of the process for UA. As they indicated in the surveys, the fee is not the only driver for their choice. Often their choice is influenced by vicinity, familiarity and language. On the other hand, this would require an increase in terms of human resources for ECHA.

5.3 Results for the policy option C: payment in instalment

This policy option consists in introducing a change in the payment conditions. The following possibility is tested:

- A payment in three instalments: 10% at the time of the introduction of the dossier, 15% the year after and 75% the following year).

The options have been tested with the estimates of the baseline scenario changing the percentage of SMEs applying. The results are provided in the tables below.

Table 5-14 Consequence for ECHA budget and EU subsidy of the implementation of a payment in three instalments with 10% SMEs applying (10% the year of the introduction of the dossier, 15% the next year and 75% the following year, in million €)

	2017	2018	2019	2020
Original revenue	7,34	11	8,39	10,12
New revenue	6,95	14,19	15,36	14,41
Costs	11,41	10,94	11,15	12,01
Original subsidy	4,07	-0,051	2,76	1,89
New subsidy	4,46	-3,25	-4,20	-2,40

Table 5-15. Consequence for ECHA budget and EU subsidy of the implementation of a payment in three instalments with 25% SMEs applying (10% the year of the introduction of the dossier, 15% the next year and 75% the following year, in million €)

	2017	2018	2019	2020
Original revenue	7,34	11	8,39	10,12
New revenue	6.38	12.60	14.23	13.94
Costs	11,41	10,94	11,15	12,01
Original subsidy	4,07	-0,051	2,76	1,89
New subsidy	5.03	-1.66	-3.08	-2.00

Table 5-16. Consequence for ECHA budget and EU subsidy of the implementation of a payment in three instalments with 50% SMEs applying (10% the year of the introduction of the dossier, 15% the next year and 75% the following year, in million €)

	2017	2018	2019	2020
Original revenue	7,34	11	8,39	10,12
New revenue	5,42	9,97	12,35	13,16
Costs	11,41	10,94	11,15	12,01
Original subsidy	4,07	-0,051	2,76	1,89
New subsidy	5,99	0,98	-1,20	-1,15

It should be taken into account that on the long term (beyond 2020) this implies no overall reduction of the contribution from the general budget of the EU to the ECHA budget as the revenue is distributed over the different years.

From the results presented in the three tables above, it is clear that for the ECHA budget, the instalments are overcompensating the gap between costs and revenues in the years 2018, 2019, 2020 if there are very little SMEs applying. The higher the number of SMEs, the more balanced the budget becomes. This has to do with the SME reduction provided and the fact that the final contribution in year N+2 (where a lower amount of costs are located) is smaller than for the large companies.

To conclude, the payment in instalments does aid in the short term to create a better balance of the ECHA budget. However, it should be taken into account that, depending on the number of submissions in the years after 2020, in the long term the total contribution from the general budget of the EU will remain at the same level. Finally, from the interviews with companies and stakeholders it was indicated multiple times that the opportunity to pay in instalments would be welcomed as this reduces the financial pressure at the start of the authorisation process. Furthermore, it would support SMEs to apply for UA as the financial threshold would reduce.

6 Conclusions

The tools developed in this study have allowed to run simulations representing several policy options.

The first option considers no change in the current Commission Implementing Regulation No 564/2013. The number of applications to Union Authorisations between 2016 and 2017 are estimated in three scenarios (baseline, optimistic and pessimistic). The simulations reveal that despite important variations in the number of applications estimated for 2020 (25 in the pessimistic scenario and 96 in the optimistic scenario), the impact on the number of ECHA staff is rather limited; around 69 FTE in the pessimistic scenario and 82 in the optimistic scenario in 2020.

Regarding the EU subsidy required to balance the ECHA budget, the simulations show more important differences between the three scenarios. A subsidy in the range of € 3 million is estimated in the pessimistic scenario and in the range of € 1.5 million for the optimistic scenario for the years 2019 and 2020.

The effect of increasing or decreasing certain ECHA fees on the budget has also been tested. It has become apparent that increasing all the fees by a maximum of 20% still does not result in a complete balance of the budget in 2020 when using the baseline scenario. If all fees are increased by 15%, it is feasible to have the EU subsidy covering only the costs under the Review Programme. It should be taken into account that some of the current fees do not cover the total cost of the corresponding activities (i.e. under Annex 1: the fee for an additional product type when a full evaluation is required, under Annex 2: the fees for same biocidal product and product family, for a recommendation on the classification of change and for an administrative change, and under Annex 3: fee for appeal). When the fees are put to a level based upon their costs plus 20% overheads and 20% horizontal costs, this implies in all simulations an increase of the EU subsidy.

A change of the annual fee has only a very limited impact on the overall budget of ECHA. If the fee would be decreased by the maximum tested (20%) it would still only require an increase of less than € 200 000 in the EU subsidy. As more products gain Union Authorisation, the revenue generated under this heading will increase substantially due to the large margin. Both in our survey as in the AISE/EBPF survey, companies have indicated the importance the annual fee plays in their choice between UA or NA+MR. The uncertainty related to the level of the annual fee and whether the annual fee for UA is cumulative to any national annual fees is an important concern.

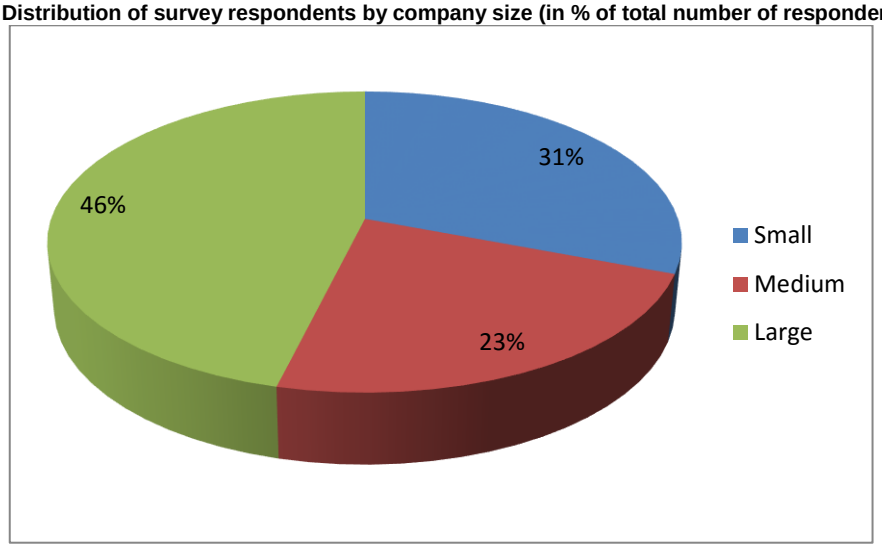
Regarding the possibility to change the payment conditions (payment in several instalments), there is no impact on the total contribution from the EU budget. It only affects the amount of the annual contribution, with an increase in the year following the implementation of the change. This option could have a positive effect for both the industry and for ECHA as it would increase the attractiveness of the Union Authorisation. SMEs could in particular be positively affected by the possibility to pay in several instalments. However, an increase in the fee for Mutual Recognition or the introduction of a new fee for First National Authorisation could have a negative impact on small companies.

Annex 1: results of the survey

Invitations to answer the survey were sent to 120 companies. They were asked to provide their answers before the 1st of December. The final number of completed surveys was 26; equalling a response rate of 22 %.

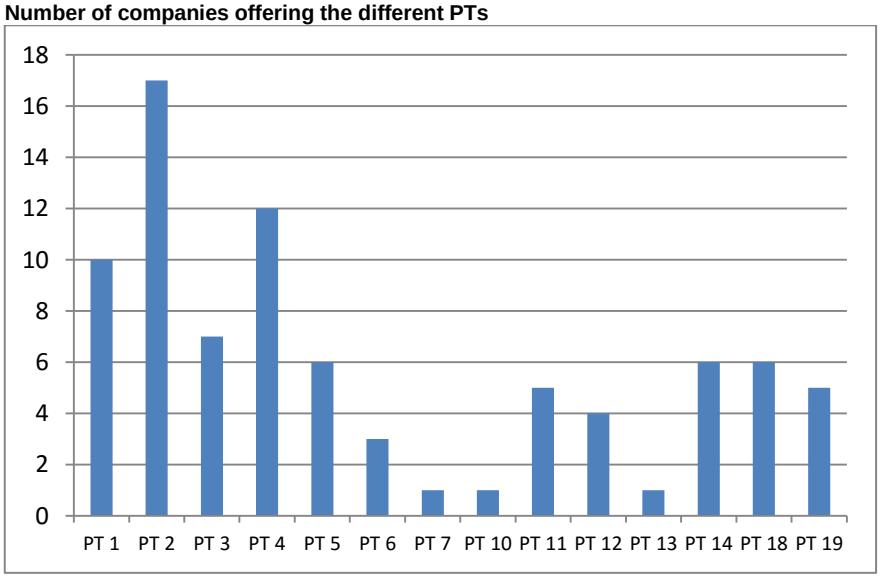
The survey included 12 companies (46 % of the respondents) categorized as large companies, figure A1-1. The respondents also included 6 medium sized companies and 8 small companies.

Figure A1-1 Distribution of survey respondents by company size (in % of total number of respondents)



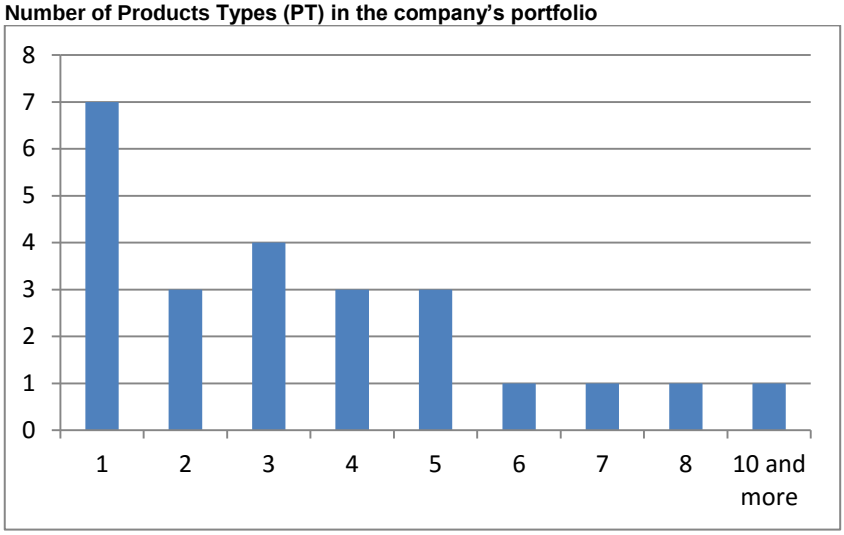
The survey covers all biocidal product types, but the PTs no. 8, 9, 15, 16 and 17 were not offered by any of the respondents. Hence, 14 Product Types were covered by the survey. The most frequent product type included in the respondents' portfolio was PT no. 2 (Disinfectants); this PT was offered by 17 out of 26 respondents. The second most important PT was no. 4 (Food and Feed area) as it was marketed by 12 companies as illustrated in the Figure A1-2.

Figure A1-2 Number of companies offering the different PTs



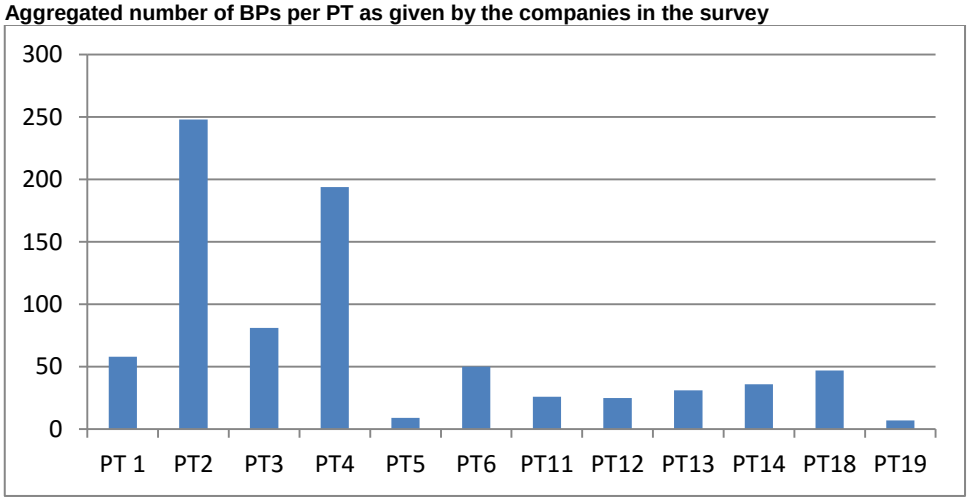
The respondents were asked to provide information about how many PTs they carried in the company's portfolio (figure A1-3). It was a very clear pattern that most of the respondents only offered 1 PT (7 out of 26 answers). Four companies offered 3 PTs, that being the most frequent number of PTs in a company's portfolio. Only one company offered more than 10 PTs. Small companies had between 1 and 6 PTs in their portfolio with 1 being the most frequent number. The medium sized companies offered between 1 and 4 PTs, and the large companies offered between 1 and 11 PTs with 4-5 PTs being the most frequent number in this category.

Figure A1-3 **Number of Products Types (PT) in the company's portfolio**



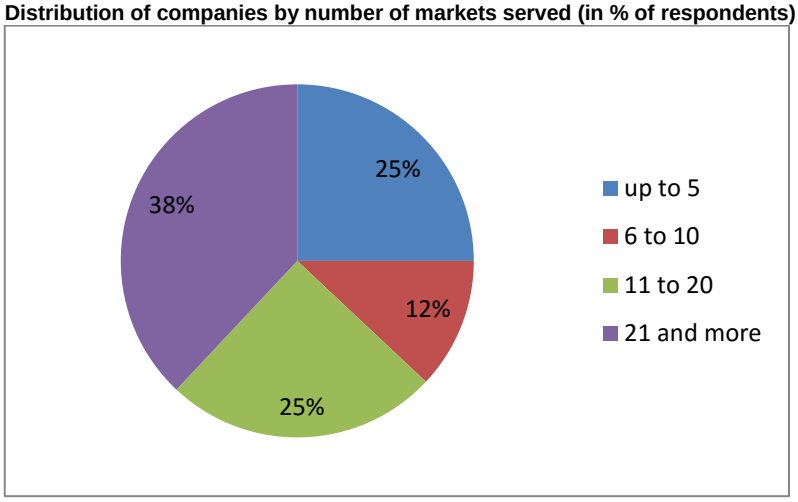
The number of biocidal products for each Product Types is provided in the figure below.

Figure A1-4 **Aggregated number of BPs per PT as given by the companies in the survey**



A majority of the surveyed companies operates in more than 21 countries (this answer was provided by 38 % of the respondents), figure A1-5 25 % of the respondents only targeted up to 5 markets or between 11 and 20 markets. Large companies tend to address between 10 and 20+ markets but, there was no significant pattern regarding the number of markets for this group of respondents. All medium sized companies were selling biocidal products in more than 20 markets. The group of small companies showed a strong trend for polarisation. Either the small companies only served 1-2 markets or they served between 10 and 20 markets. This could be related to the fact that some of the small companies were only operating in the domestic market whereas others offered a product that was applicable to a large number of markets.

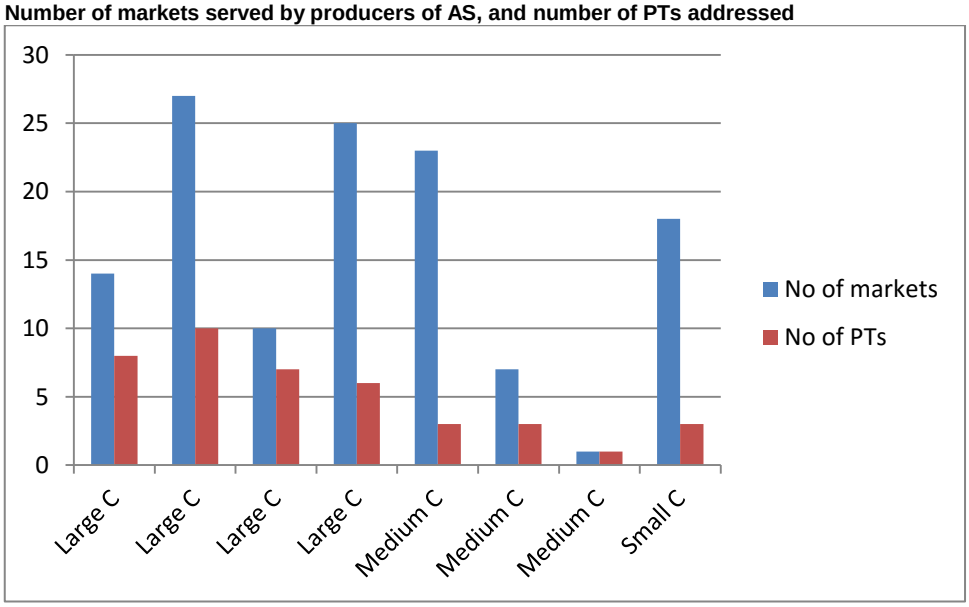
Figure A1-5 Distribution of companies by number of markets served (in % of respondents)



Findings on the dynamics for Active Substances

Out of 27 surveyed companies, 8 produce and commercialise Active Substance (AS), including 4 large companies, 3 medium-sized companies, and 1 small company. These 8 companies supply AS across the EU markets as illustrated in the figure A1-6. Large companies supply between 14 and 27 markets, whereas the medium-sized companies supply between 1 and 23 markets. The survey showed that large companies generally produced AS for a higher number of PTs than medium-sized and small companies. The largest number of PT addressed by a producer was ten PT.

Figure A1-6 Number of markets served by producers of AS, and number of PTs addressed



The companies producing AS indicated that it took between 5 (most common) and up to 15 years to develop a new AS. Producers of AS mentioned that the time for RoI[25] for an AS was between 2 years (minimum) and up to 15 years (maximum). This indicates that the development of an AS is a long-term process. A large company indicated *"The investments in the data package and the evaluation fee are huge, and the profit on our product is not that high, so it will take between 7 and 10 years to earn this investment back"*.

The survey showed that all companies operating within the AS segment experienced product drop-out of the market as illustrated in the table below:

[25] RoI defined as time from development of the AS is initiated to the AS generates income to the company.

Table A1-1. Drop-out of AS, by company

Respondent	Drop-out rate AS	No. of markets
Large	0-10 %	14
Large	n.a.	27
Large	+ 50 %	10
Large	20-30 %	25
Medium	10-20 %	23
Medium	0-10 %	7
Medium	20-30 %	1
Small	0-10 %	18

Companies provided the following reasons for AS drop-out:

- The AS was old and established (alcohol);
- Not gaining authorisation due to environmental reasons;
- Negative changes in the authorisation could impact decisions about withdrawing the AS.

Only one company in the survey (medium-sized with wide market coverage) claimed to have 6 new AS in its portfolio. A large company responded that one new AS was introduced every 2-4 years. Overall, the survey showed that the producers of AS were anticipating the overall number of AS in the market would decrease in the coming years. The most important argument for this was an increasing pressure from regulatory and environmental authorities and increasing costs. Another trend is that the number of AS is not expected to increase; rather the application of the AS would be expanded to more PT. From these answers it is clear that the AS producers are developing (few) new AS but, the overall number of AS in the market will decline in the coming years.

Findings on the dynamics for Biocidal Products

The companies provided answers as to the time it takes to develop a new BP and the Return on Investment (RoI which represents the time for gaining return on this investment). Overall, the development time for a new BP is between 1 and 3 years with 2 years being the most common time (as replied by 9 out of 25 respondents). There is no significant difference when it comes to the development time of large companies compared to that time of other company sizes. According to the survey, the factors that influence the development time are:

- The product type itself i.e. PT 4 takes a long time due to severe testing and documentation procedures (mandatory data requirements from the BPR regulation);
- The BP itself i.e. a toilet bleach is less complicated to develop that a foaming cleaner for kitchens;
- The development itself i.e. if both a new AS and a new BP is to be developed it takes a long time;
- The way the BP is intended to be used;
- Stability testing can take a long time.

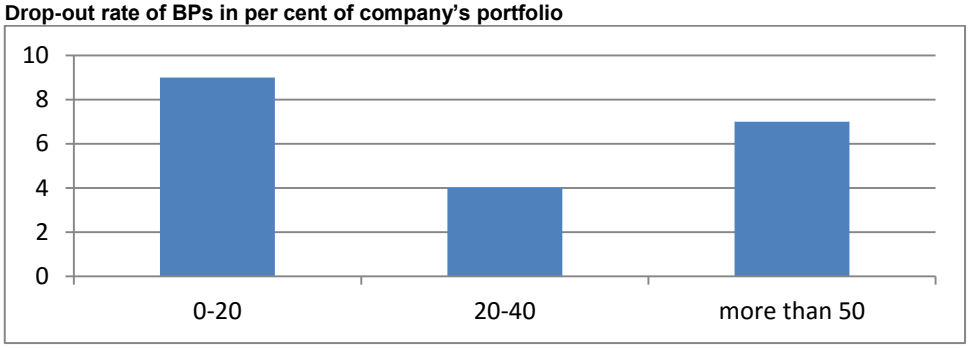
The RoI varies between product types but not with a particular pattern. The companies in the survey have replied that RoI may be shorter than the development time (as replied by 5 companies), and three companies have claimed a RoI of 10 years (for PTs with a development time of two or five years, respectively).

The RoI also seems to vary according to the application or market. This implies that for BPs of the product types 14 and 18 the RoI have been mentioned to be rather short by the respondents, but, it is not significant. For companies providing well-known BPs in the consumer market (e.g. flea collars for dogs) the RoI is 1-2 years. A major challenge for producers of BPs is the unfavourable balance between the volume of the BPs sold in the market compared to the development and registration

costs. From the survey, this balance was evident in more responses but, no quantitative data have been provided.

BPs tend to drop out of the market for a number of reasons, but the most frequently reason mentioned in the survey (8 out of 20 responses) are the costs for renewal or registration of BPs. The figure A1-7 shows the drop-out rate for BPs and, it can be seen that companies either tend to maintain the majority of the product portfolio (given by the drop-out rate of 0-20 %) or, reduce the portfolio significantly (drop-out of + 50 per cent).

Figure A1-7 **Drop-out rate of BPs in per cent of company's portfolio**



The decisions to withdraw a BP from the market are dependent on company sales strategies, experiences in the market and, general competition issues. Among the reasons reported for reducing the portfolio, companies indicated that the BPR will lead to a harmonised market with fewer BPs and that it becomes a necessity to align their portfolio across countries.

Findings on different attitudes towards Union Authorisation (UA)

Here an analysis of the answers of different companies on their general attitudes towards UA should be enlightened. This can be based on their company size and the numbers of markets they are active in, the PTs they produce and the Return on Investment rates related to the development time of BPs (diversify across PTs).

The survey clearly shows that the respondents either favour or not favour UA – there is no in-between attitude. Table A1-2 shows the most frequent reasons for favouring or not favouring UA.

Table A1-2 **Most frequent reasons for favouring or disfavouring UA for BPs**

Reasons for favouring UA	Reasons for dis-favouring UA
The company sells (via distributors) to all Member States	It is the company's strategy to sell only in selected markets
The company has sales in +20 EU markets	The company only sells in the local market
The company has only few products in the portfolio	AS used so far are candidates for substitution
The company produces for private labels and branded products for sale in all Member States	The product type (PT18, rodenticides) is not eligible for UA
The company is in favour of a harmonized market	The RoI on the products is very low

All companies from the survey stated that the fees were high or too high. The costs for authorisation compared to development costs for BPs are too high. This was very clear from the survey and evident across company sizes and product types. Only three respondents (two medium-sized companies and a large one) regarded this relation as "medium". These respondents had sales in most markets across the EU but, they only offered between two and four product types. This indicates that there could be coherence between a low number of product types (thus relatively low development costs) and high number of markets (thus speeding up RoI) for considering the relation between development costs

and authorisation costs as “appropriate”. It was evident from the responses that companies did not agree with the present fee level as these quotes from the survey shows:

- *Our highest development costs for a product are less than 30 % of the expected authorization cost. For most of the products development is about 10 % or less of the authorization costs;*
- *The costs for the registration fee are € 350 000 and we can expect sales of € 35 000 (we operate in a small market), so the fee is killing our industry;*
- *The development costs are incremental compared to the registration fee;*
- *Authorisation fees are 5-25 times higher than the development costs and can only considered reasonable for product families, not for product types.*

There is also spatial element to this discussion. Countries such as Denmark and Sweden do not seem to be chosen for registration of BPs (due to high fee levels), and countries in South and Central Europe are more favoured in this respect.

One respondent claimed that there should be a balance between the workload coming with a registration, so a simple registration should be less costly compared to a more complicated registration. The United Kingdom was mentioned here as an example of a good system for a differentiated approach to the fee level. Also the Netherlands was mentioned as a country with transparency of the work carried out and the payment.

From some responses it was clear that a few EU Regulations affecting quite similar product(s) or product groups impact the companies very differently. One company claimed that if the product was registered as a BP a changed formulation would impose a fee of € 80 000, whereas the same product could be reformulated as a cosmetic product for € 1 000. The company also stated that when registering a product as a new BP it would cost a fee of € 100 000 in comparison to € 5 000 for a cosmetic product. Another company stated that if a product was not registered as a BP but as a “bleaching agent” there was no registration fee. There is a need for adjusting different Regulations to find a more balanced approach to fee levels.

Companies show some discouragement when it comes to the balance between the fee level and the work carried out by ECHA. The survey showed that some companies felt there was no transparency of the work carried out for the registration fee, as most of the work was carried out by national authorities. Other statements were related to dissatisfaction with the annual fees of € 20 000. This fee level is considered too high compared to sales and expected RoI.

When asked the question of choosing either National Authorisation (NA) or Union Authorisation (UA) the companies generally favour NA when only a limited number of markets are served. There is also strong agreement among the respondents that the outcome of a UA compared to NA/MR is more uncertain. From the survey results, the threshold for choosing UA is sales in more than 20 EU markets. Companies state the following arguments for choosing UA over NA combined with Mutual Recognition (MR):

- When going for the UA, the risk of losing markets is less than if the company goes for NA/MR. It is explained by the complications arising from dealing with a number of national authorities rather than a single authority;
- The Family Procedure is recognized by some respondents as a driver for choosing UA in comparison to NA/MR. Some of the respondents claimed that the Family Procedure is more costly than going for NA/MR for all products. One respondent indicated that a fee of € 500 000 for a Product Family authorisation seemed quite expensive when sales were expected to be between € 20 000 and€ 1 500 000 depending on the product and the market.

The experience in dealing with LoA seems to have some influence on the respondents' answers. In those cases were this procedure is seen as "uncomplicated", the respondents state that they have been acquiring or issuing LoAs in several years, and that this procedure including access to data have been well-functioning. The positive answers are primarily stated by large companies. For those companies that consider the LoA procedures in a negative way, the responses are to a high degree related to the time and trouble related to obtain the necessary data. In addition, costs for lawyers and lack of insights to what is required for this procedure seem to have biased this group of answers.

Concerning the organisation of the authorisation procedure, the survey showed a strong consensus of the fact that ECHA as a one-stop-shop for UA is relevant and/or important. Only 1 company disagreed to this statement. The introduction of the Biocidal Product Family concept (BPF) is generally recognized as a positive measure by the companies in the survey.

The companies in the survey point to some challenges connected with the BPF concept such as:

- The number of products needs to be more than three products;
- With nine products the BPF for UA stills seems to be more expensive than NA/MR.

Future outlook

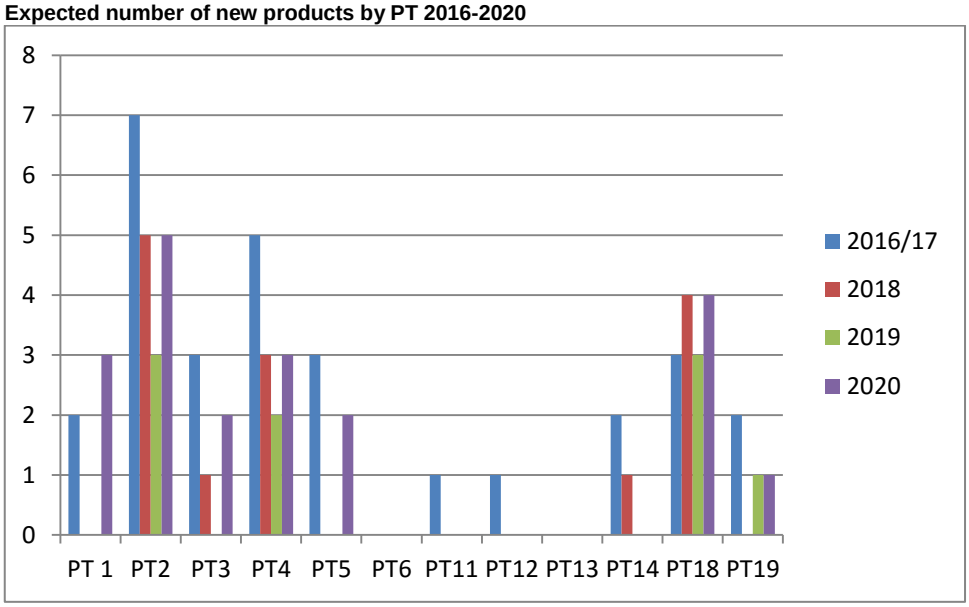
The survey showed that the high level of fees for registration compared to the development costs had a negative impact on companies' willingness to innovate. But, on the other hand, the survey also showed that the companies in this industry already has a pipeline of new products that are to be introduced in the market during the coming years. This is relevant for companies of all sizes. Table A1-3 shows the expected number of new products introduced in the BP market and the expected number of UAs for the new products. It is a fact from the survey that the respondents who are anticipated to decide for UA all belong to the group of large companies.

Table A1-3 Expected number of new biocidal products and expected number of UAs for these products

	2016/17	2018	2019	2020
Expected number of new products	178	55	59	839
Expected number of UAs for the new products	119	6	22	777
UAs in per cent of number of new products	67 %	10 %	37 %	92 %

Particularly within PT2 (disinfectants), PT4 (food and feed area) and PT18 (insecticides), a comprehensive number of new products are foreseen to be introduced into the EU market between 2016 and 2020, figure ss. No innovations are foreseen by the respondents for the PTs no. 6 and 13, and the innovation within PTs no. 11 and 12 are very limited, too. The large companies in the survey have indicated to be innovative within a higher number of PTs compared to the medium-sized and small companies.

Figure A1-8 Expected number of new products by PT 2016-2020



Producers of AS reveal that, the number of new active substances to be introduced until 2020 ranges between 5 and 10 compounds. Some of the new ASs are destined for PT 14 and 18.

Additional findings on the costs related to the BPR: result of in-depth interviews

In order to estimate the overall costs of the industry for placing biocides on the EU market, 3 interviews have been conducted with a representatives of three different sizes of companies: small, medium and large. The assumption is that the size influences the importance of different types of costs European companies at the biocidal markets have to face and impacts directly their business strategies. Since the companies revealed some sensitive business information, their answers are presented anonymously and summarized in three different sections, including the information about the company itself and the market the respective company operates on. The last section of this chapter presents the main conclusions from the interviews, related to the cost companies face while manufacturing and or/trading biocides in the EU.

a. Small company

The small company has the following characteristics:

- Less than 50 employees and € 10 million turnover/balance sheet;
- Being active in one MS;
- Marketing biocide from one PT;
- Sells products to professional users.

The company indicated that development of a BP takes approximately 2 years and RoI is between 2 and 4 years. The **development costs** are estimated **to 300 thousand EUR** – the company finds the costs relatively low and attributes them to the fact that the used AS is already available at the market and no further testing is needed. The authorization costs pose around 20 to 25% of total costs of bringing the product to the market and this amount is considered as stable. The amount includes the consultant that took care of the management of the dossier.

When it comes to **dossier preparation**, it starts after a year from the start of the development, in other words in the middle of the development period. Around 4 to 5 people, researchers and administrators, are involved in the preparation. In the costs of the dossier preparation, 60% are attributed to personal costs. The company gained the letter of access for free. No case of dossier refusal, resulting in sunk costs has been experienced.

The company sells around 60 to 70 thousand litres of the BP per months and estimates the monthly profit, in other words **opportunity costs** of monthly delay to € 10 thousand a month. The company doesn't have information about its share at different MS markets. The opportunity costs are less relevant to this company since it has no aspirations to move to other MS markets, uses its own country's CA and thus doesn't face the choice of authorization routes.

b. Medium company

The medium company has the following characteristics:

- More than 50 employees and € 50/43 million turnover/balance sheet;
- Being active in 26 EU MS (BP and AS);
- Produces 6 types of AS and 5 types of BP;
- Sells products to professional and industrial users.

The company purchases formulations of AS and thus doesn't have experience with their development. The RoI for AS is steadily three years. Development of a BP takes approximately three years. Before BPR, the development had been shorter, about 1 year – what influences the time needed are the stability studies. The **development costs** are estimated **to € 50 to 200 thousand**. The increase is attributed to the BPR. The costs can be compared for example to the USA where producers also face highly regulated environment. The authorization costs pose 50% of total costs of bringing the product to the market. Company opts for ECHA authorization route since the combination of MR and NA is too difficult to manage and lengthy, bringing high opportunity and administrative costs.

When it comes to **dossier preparation** it takes one year and starts approximately after two years from the start of the development. The company employs four people, two researchers, administrators and marketing assistant, who are full time involved in dossier preparation. Costs of one dossier preparations are estimated to € 50 thousand of personal costs. The company faces a lot of issues with the IT system that bring extra personal costs. For the letter of access, the costs vary between € 50 thousand to 600 thousand depending on the number of companies getting the letter of access for the same latter of access.

The company didn't share the information about the **opportunity costs** and other market related information. The company uses external consultancy for external evaluation and estimates its costs up to 30% of the total costs of the dossier preparation.

c. Large company

The large company has the following characteristics:

- More than 50 employees and € 50/43 million turnover/balance sheet;
- Being active in all 28 EU MS (BP);
- Produces BP for 9 Product Types;

Sells products to professional users.

The company doesn't produce any AS, however is very active at the market of BP in the EU and internationally. It estimates quite wide range of RoI on BP between 0.5 and 5 years depending on the type of product. The **development** of a new BP takes approximately two years. The company that is selling wide range of products at the EU market explained that currently the development of new products has been inhabited since the current research capacities are occupied with product innovation and transition to BPR that indeed consumes a lot of human and financial resources, since the company has to authorize a huge portfolio of BP.

The company estimated its total costs to develop a new BP as high as € 2 million, under a premise that the product will be sold globally. Concerning the dossier preparation for authorization under BPR, the high administrative and especially **opportunity costs** have been pointed out. The company mentioned that while the BP authorisation costs are payable at the beginning of the evaluation process, the evaluation needed before the product can be marketed at the EU market can take up to three years. Further opportunity costs arise due to the costs of the review programme of AS for the company and related diminishment of the RoI.

Since the company has around 300 to 400 BP that are to be authorised by 2020. This high amount that must go through the evaluation (and the appropriate fees must be paid) puts high pressure on the human resources and also requires high level of financial resources to be put forward. This pressure may result in as high as 50% of the current portfolio of the company to be dropped from the EU market.

Annex 2: estimates of the number of applications to Union Authorisation

Estimates for the year 2016

Table 0-1 Reasoning supporting estimates for Union Authorisation in 2016

Active substances with deadline in 2016	PTs	Outcome RP (based on the Commission Implementing Regulations)	Results from MSCA data on approved BPs	Results from survey	Estimates 2016		
					PS	BS	OS
Permethrin	18	The official data of approval is 1 May 2016. As pre-submissions are advised to be made at least 6 months before the deadline, only submissions without pre-submission consultation can be made. Expectations are however that this amount will be limited. Permethrin is not considered a candidate for substitution. However, it might have endocrine disrupting characteristics and will be further assessed by the PBT expert group.	The available data[26] on authorised products of the MSCAs indicates that around 2600 BPs are currently on the market containing permethrin. These are underestimates as the data of the MSCAs are not complete and a number of MS data was not available at this level of detail.	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA of which only 10% would opt for the BPF option.	1	2	3
Propan – 2 ol	1, 2, 4	The official date of approval is 1 July 2016. As pre-submissions are advised to be made at least 6 months before, the chance of receiving additional pre-	The available data[27] on authorised products of the MSCAs indicates that around 1800 BPs are currently on the market containing propan-2-ol. These	The AS can be used in 3 PT for which the industry declared intention to opt for UA (PT2 in particular but also 1 and 4).	2 + 9 families	3 + 9 families	3 + 10 families

[26] Only the data from the UK, Belgium, the Netherlands, Estonia, Latvia, Slovenia, Croatia, Spain, Poland, Sweden, Cyprus, Finland, Greece, Germany and France had BPs which have Permethrin. Data presented is based on these numbers

[27] Only the data from the UK, Belgium, the Netherlands, Estonia, Latvia, Slovenia, Croatia, Spain, Poland, Sweden, Cyprus, Finland, Greece, Germany and France had BPs which have Permethrin. Data presented is based on these numbers

Active substances with deadline in 2016	PTs	Outcome RP (based on the Commission Implementing Regulations)	Results from MSCA data on approved BPs	Results from survey	Estimates 2016		
					PS	BS	OS
		submissions is limited. Propan-2-ol is not considered a candidate for substitution.	are underestimates as the data of the MSCAs are not complete and a number of MS data was not available at this level of detail. Most of these products fall under PT02 (60%).				
Clothianidin (in combination with pyriproxyfen)	18	The official date of approval is 1 October 2016. As pre-submissions are advised to be made at least 6 months before, submissions can still be made until April. Clothianidin is a candidate for substitution[28]. There were no comments received during the public consultation and the remark was published that there are alternative AS which are already approved.	The available data[29] on authorised products of the MSCAs indicates that around 15 BPs containing Clothianidin are currently on the market. These are understimates as the data of the MSCAs are not complete and a number of MS data was not available at this level of detail.	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA of which only 10% would opt for the BPF option.	1	1	2
Glutaraldehyde (in combination with CMIT/MIT)	2, 3, 4, 6	The official date of approval is 1 October 2016. As pre-submissions are advised to be made at least 6 months before, submissions can still be made until April. Glutheraldehyde is considered to be a candidate for substitution by being a respiratory sensitiser[30].Three comments were	The available data[31] on authorised products of the MSCAs indicates that around 800 BPs are currently on the market containing glutaraldehyde. Only a very small number (max. 10) has the combination with CMIT/MIT. Up to 60% of these BPs fall under PT02. These are underestimates as the data of the	The AS can be used in 3 PT for which the industry declared intention to opt for UA (PT2 in particular but also 3 and 4). No interest declared for UA for PT 6 so far.	1 + 1 family	2 + 1 family	3 + 2 families

[28] Art. 10 (1) (a, b and d) of Reg. (EU) 528/2012
[29] Only data from Spain, Greece and France had information on BPs containing Clothianidin.
[30] Art. 10 (1) (b) of Reg. (EU) 528/2012
[31] Only the data from Belgium, the Netherlands, Estonia, Latvia, Slovenia, Croatia, Spain, Poland, Sweden, Cyprus, Germany and France had BPs which have Glutaraldehyde. Data presented is based on these numbers

Active substances with deadline in 2016	PTs	Outcome RP (based on the Commission Implementing Regulations)	Results from MSCA data on approved BPs	Results from survey	Estimates 2016		
					PS	BS	OS
		received during the public consultation of which only one emphasised the essentiality of the AS. In the conclusion it is mentioned that there are other active substances with similar intended uses	MSCAs are not complete and a number of MS data was not available at this level of detail.				
Alpha-Cypermethirin	18	The official date of approval is 1 July 2016. As pre-submissions are advised to be made at least 6 months before, the chance of receiving pre-submissions is very small. Alpha-Cypermethirin is not considered a candidate for substitution.		Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA of which only 10% would opt for the BPF option.	0	0	0
Bacillus spaericus 2362, strain ABTS-1743	18	The official date of approval is 1 July 2016. As pre-submissions are advised to be made at least 6 months before, the chance of receiving pre-submissions is very small.		Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA of which only 10% would opt for the BPF option.	0	0	0
Bacillus thuringiensis subsp. Israelensis, strain SA3A	18	The official date of approval is 1 July 2016. As pre-submissions are advised to be made at least 6 months before, the chance of receiving pre-submissions is very small.		Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA of which only 10% would opt for the BPF option.	0	0	0

Active substances with deadline in 2016	PTs	Outcome RP (based on the Commission Implementing Regulations)	Results from MSCA data on approved BPs	Results from survey	Estimates 2016		
					PS	BS	OS
MIT	13	The official date of approval is 1 October 2016. As pre-submissions are advised to be made at least 6 months before, submissions can still be made until April. MIT is not considered a candidate for substitution.		No interest declared for UA for PT13. BPs falling under PT13 are not eligible for UA until 2017.	0	0	0
IPBC	13	The official date of approval is 1 December 2016. Pre-submissions can still be received until 1 June 2016. IPBC is not considered a candidate for substitution.		No interest declared for UA for PT13. BPs falling under PT13 are not eligible for UA until 2017.	0	0	0
DCPP	1, 2, 4	The official date of approval is 1 December 2016. Pre-submissions can still be received until 1 June 2016. DCPP is considered to be a candidate for substitution. No comments were received during the public consultation. A comparative assessment is thus required when authorisation is requested.	The available data[32] on authorised products of the MSCAs indicates that around 55 BPs containing DCPP are currently on the market. These are understimates as the data of the MSCAs are not complete and a number of MS data was not available at this level of detail.	The AS can be used in 3 PT for which the industry declared intention to opt for UA (PT2 in particular but also 1 and 4). BPs falling under PT02 are only eligible for UA from 2017 onwards.	1	2	3
L-(+)-lactic acid	1	L-(+)- lactic acid is a new active substance under the BPD. L-(+)- lactic acid is not considered a candidate for substitution.	New, currently no BPs on the market. There is thus also no deadline for UA applications.				

[32] Only data from Latvia, Slovenia, Croatia, Germany, Cyprus and France had information on BPs containing DCPP.

Estimates for the year 2017

Table 0-2 Reasoning supporting estimates for Union Authorisation in 2017

Active substances with deadline in 2017	PTs	Outcome RP (based on the Commission Implementing Regulations)	Results from MSCA data on approved BPs	Results from survey	Estimates 2017		
2-biphenylol	1,2,3,4,6,13	2-biphenylol is not a candidate for substitution[33].	The available data[34] on authorised products of the MSCAs indicates that around 250 BPs are currently on the market. This number is an underestimate due the regulatory transition period and missing data. Most BPs with this AS fall under PT02	The AS can be used in 4 PT for which the industry declared intention to opt for UA (PT2 in particular but also 1,3 and 4). No interest declared for UA for PT 6 and 13	1 + 1 family	2 + 2 family	4 + 3 family
Hydrogen peroxide	1,2,3,4,5,6	Hydrogen peroxide is not a candidate for substitution.	The available data[35] on authorised products of the MSCAs indicates that around 2340 BPs are currently on the market. This number is an underestimate due the regulatory transition period and missing data. Most BPs with this AS fall under PT02 (75% of all BPs).	The AS can be used in 5 PT for which the industry declared intention to opt for UA (PT2 in particular but also 1,3,4 and 5). No interest declared for UA for PT 6	7+ 8 family	7 + 10 families	10 + 15 families
Peracetic acid	1,2,3,4,5,6	Peracetic acid does is not a candidate for substitution.	The available data[36] on authorised products of the MSCAs indicates that around 920 BPs are currently on the market. This number is an underestimate due the regulatory transition period and missing data. Most BPs with this AS fall under PT02 and/or PT04 (54% and	Same as for Hydrogen peroxide	3 +5 families	4 + 7 families	6 + 9 families

[33] Art. 10 (1) (a, b, d, e and f) of Reg (EU) 528/2012

[34] Only the data from Belgium, Estonia, Latvia, Slovenia, Croatia, Spain, Germany and France had BPs which have 2-biphenylol. Data presented is based on these numbers

[35] Only the data from Belgium, the Netherlands, Estonia, Latvia, Slovenia, Croatia, Spain, Cyprus, Germany and France had BPs which have hydrogen peroxide. Data presented is based on these numbers

[36] Only the data from Belgium, the Netherlands, Estonia, Latvia, Malta, Slovenia, Croatia, Spain, Cyprus, Sweden, Poland, Germany and France had BPs which use peracetic acid. Data presented is based on these numbers.

Active substances with deadline in 2017	PTs	Outcome RP (based on the Commission Implementing Regulations)	Results from MSCA data on approved BPs	Results from survey	Estimates 2017		
			30%of all BPs). This Active Substance is often used in combination with hydrogen peroxide and often covers multiple PT. It is thus highly likely that UA for Product Families will be requested.				
Ampholyt 20	2,3,4	Ampholyt 20 is not a candidate for substitution.	The available data[37] on authorised products of the MSCAs indicates that around 20 BPs are currently on the market. This number is an underestimate due the regulatory transition period and missing data.	The AS can be used in 3 PT for which the industry declared intention to opt for UA	1	1	2
CMIT/MIT	2,4,6, 11, 12, 13	CMIT/MIT is not a candidate for substitution. It is classified as a skin sensitizer. Some of the opinions were adopted by simple majority vote (PT2, , 4, 6, 13)	The available data on authorised products of the MSCAs indicates that around 20 BPS are currently on the market. This number is an underestimate due to the regulatory transition period and missing data.	The AS can be used in 2 PT for which the industry declared intention to opt for UA	1	1	2
PHMB	2,3,4	PHMB is a candidate for substitution[38]. From the public consultation the comments were that there are currently AS being reviewed under Reg. (EU) 528/2012 intended for use under the same PTs.	-	The AS can be used in 3 PT for which the industry declared intention to opt for UA	0	0	1

[37] Only the data from UK, the Netherlands, Latvia, Slovenia and Croatia had BPs which use Ampholyte 20. Data presented is based on these numbers
[38] Art. 10 (1) (d) of Reg. (EU) 528/2012

Active substances with deadline in 2017	PTs	Outcome RP (based on the Commission Implementing Regulations)	Results from MSCA data on approved BPs	Results from survey	Estimates 2017		
Bacillus amyloliquefaciens	3	The AS is not a candidate for substitution.	No BPs found in the data made available by the MSCAs on Bacillus amyloliquefaciens.		0	0	0
DBDCB	6	DBDCB is not a candidate for substitution.		No interest declared for UA for PT6	0	1	1
Cyromazine	18	Cyromazine is not a candidate for substitution.		Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA of which only 10% would opt for the BPF option.	0	0	1

Estimates for the year 2018

Table 0-3 Argumentation for estimated no. of submissions for UA based on the progress of the Review Programme in 2018

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
Calcium oxide / lime / burnt lime / quicklime	2, 3	Only in France, 4 under PT02 and 8 under PT03.	1 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	25%[39]	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	0	0	0
Calcium dihydroxide / calcium hydroxide / caustic lime / hydrated lime / slaked lime	2, 3	Only in France, 13 BPs in total 4 PT02, 5 PT02 and 03 and 4 PT03	1 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	25%[40]	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	0	0	0
Calcium magnesium tetrahydroxide / calcium magnesium hydroxide / hydrated dolomitic lime	2, 3	Only in France 7 BPs under PT02 and Germany 1 BP under PT03	2 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	25%[41]	A high percentage of products will be placed on the market under BPFs rather than as separate products.	0	0	0

[39] Based on the results of the surveys.
[40] Based on the results of the surveys.
[41] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
						According to the AISE/EBPF survey 60% of dossiers will be BPF.			
Calcium magnesium oxide / dolomitic lime	2, 3	Only in Germany 16 BPs under PT03.	1 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	25%[42]	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	0	0	0
Peracetic acid generated from tetra-acetylethylenediamine (TAED) and sodium percarbonate	2, 3, 4	Only data in the Netherlands, 3 BPS in total 2 under PT03 and 1 under PT04	1 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	30%[43]	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	0	0	0
Citric acid	1	Only data on the use of this AS in BPs in France (16 BPs under PT01), Latvia (1 BP under PT01), Poland (1 BP	5 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR. Over 50% of the dossiers would be sent for UA.	20%[44]	A high percentage of products will be placed on the market under BPFs rather than as	0	0	0

[42] Based on the results of the surveys.
[43] Based on the results of the surveys.
[44] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
		under PT01), Spain (6BPs under PT02) and the Netherlands (1BP under PT02)				separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.			
Cyfluthrin	18	The available data shows that there currently are around 54 BPs on the market[45]	8 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[46]	Around 70% would choose for BPF.	0	0	0
Piperonylbutoxide (PBO)	18	The available data shows that there currently are around 695 BPs on the market[47]	13 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA..	40%[48]	Around 70% would choose for BPF.	0	0	0
Cyanamide	3, 18	The available data shows only four BPs on the market, 2 under PT18 in Latvia and 2 under PT 03 in Germany.	2 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only	40%[49]	Around 70% would choose for BPF.	0	0	0

[45] Based on the data from Belgium, the Netherlands, Latvia, Croatia, Germany, Spain, Cyprus and Greece.
[46] Based on the results of the surveys.
[47] Based on the data from Belgium, the Netherlands, Latvia, Croatia, Germany, Spain, Cyprus, Finland, Slovenia, Malta, Estonia, France and the UK.
[48] Based on the results of the surveys.
[49] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
				17% of the products would apply for UA.					
CMK	1, 2, 3, 6, 9, 13	No products found in the available data.	-	-	-	-	0	0	0
Sodium hypochlorite	1, 2, 3, 4, 5	The available data shows that there are currently 3833 BPs on the market under various PTs[50].	15 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	30%[51]	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	2+2 families	4+4 families	7+8 families
Calcium hypochlorite	1, 2, 3, 4, 5	The available data shows that around 240 BPs containing calcium hypochlorite are on the market under various PTs[52].	12 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	30%[53]	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	0	0	1

[50] Based on the data from Belgium, the Netherlands, Latvia, Croatia, Germany, Spain, Cyprus, Finland, Slovenia, Malta, Estonia, Poland, Portugal, France and the UK.
[51] Based on the results of the surveys.
[52] Based on the data from Belgium, the Netherlands, Latvia, Croatia, Germany, Spain, Cyprus, Slovenia, Malta, Estonia, Poland and France.
[53] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
Chlorine	2, 5	The available data shows that around 43 BPs containing calcium hypochlorite are on the market under various PTs[54].	6 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	25%[55]	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	0	0	0
ATMAC/TMAC	8	It is unlikely that ECHA will receive any submissions for Union Authorisations for BPs containing this AS as the phasing in approach only makes UA possible for PT 8 in 2020. Industry has clearly indicated the importance of the duration and certainty of the outcome of the authorisation process. Therefore, we have taken the conservative assumption that for products containing this AS and falling under PT 8 no submissions will be made. This does not imply that the option for provisional union authorisation will not be used at all. Yet based on the available information at this time, industry does not express any interest.							
Diamine	8	It is unlikely that ECHA will receive any submissions for Union Authorisations for BPs containing this AS as the phasing in approach only makes UA possible for PT 8 in 2020. Industry has clearly indicated the importance of the duration and certainty of the outcome of the authorisation process. Therefore, we have taken the conservative assumption that for products containing this AS and falling under PT 8 no submissions will be made. This does not imply that the option for provisional union authorisation will not be used at all. Yet based on the available information at this time, industry does not express any interest.							
Acetamiprid	18	The available data shows that around 302 BPs containing calcium hypochlorite are on the market[56].	12 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[57]	Around 70% would choose for BPF.	0	0	0

[54] Based on the data from Latvia, Croatia, Germany, Cyprus, Estonia and France.
[55] Based on the results of the surveys.
[56] Based on the data from France, Sweden, Germany, Slovenia, Latvia, Portugal, Spain, Croatia, the Netherlands, Cyprus, the UK and Belgium.
[57] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
Peracetic acid	11, 12	It is unlikely that ECHA will receive any submissions for Union Authorisations for BPs containing this AS as the phasing in approach only makes UA possible for PT 11 and 12 in 2020. Industry has clearly indicated the importance of the duration and certainty of the outcome of the authorisation process. Therefore, we have taken the conservative assumption that for products containing this AS and falling under PT 11 and/or 12 no submissions will be made. This does not imply that the option for provisional union authorisation will not be used at all. Yet based on the available information at this time, industry does not express any interest.							
Active bromine generated from bromine chloride	11	It is unlikely that ECHA will receive any submissions for Union Authorisations for BPs containing this AS as the phasing in approach only makes UA possible for PT 11 in 2020. Industry has clearly indicated the importance of the duration and certainty of the outcome of the authorisation process. Therefore, we have taken the conservative assumption that for products containing this AS and falling under PT 11 no submissions will be made. This does not imply that the option for provisional union authorisation will not be used at all. Yet based on the available information at this time, industry does not express any interest.							
Cypermethrin	18	The available data shows that around 1800 BPs containing cypermethrin are on the market[58].	12 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[59]	Around 70% would choose for BPF.	1 family	1+1 family	2 families
Empenthrin	18	The available data shows that around 200 BPs containing empenthrin are on the market[60].	9 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[61]	Around 70% would choose for BPF.	0	0	0

[58] Based on the data from France, Sweden, Germany, Slovenia, Latvia, Portugal, Spain, Croatia, Cyprus, the UK, France and Belgium.
[59] Based on the results of the surveys.
[60] Based on the data from Belgium, Estonia, Latvia, Malta, Slovenia, Croatia, Germany, Spain and Cyprus.
[61] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
Icaridine	19	The available data shows that around 500 BPs containing Icaridine are on the market[62].	10 out of 19 markets	In both surveys none of the respondents expressed interest in UA for their products falling under PT19.	30%[63]	Around 70% would choose for BPF.	0	0	0
Azamethiphos	18	The available data shows that around 230 BPs containing azamethiphos are on the market[64]	12 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[65]	Around 70% would choose for BPF.	0	0	0
Mixture of cis- and trans-p-menthane-3,8 diol (Citrodiol)	19	The available data shows that around 100 BPS containing citriodiol are currently on the market[66]	5 out of 19 markets	In our survey none of the respondents expressed interest in UA for their products falling under PT19.	30%[67]	Around 70% would choose for BPF.	0	0	0
Pyrethrins and Pyrethroids	18, 19	The available data shows that around 1750 BPs containing pyrethrins and pyrethroids are currently on the market[68]	12 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT.	40%[69]	Around 70% would choose for BPF.	1 family	1+1 family	2 families

[62] Based on the data from France, Sweden, Germany, Latvia, Portugal, Spain, Cyprus, Denmark, Finland and Belgium.
[63] Based on the results of the surveys.
[64] Based on the data from Belgium, the UK, the Netherlands, Latvia, Malta, Slovenia, Croatia, Germany, Spain, Sweden, Cyprus and Denmark.
[65] Based on the results of the surveys.
[66] Based on the data from 19 MSCAs BPs containing this AS are only reported in the following 5 MSs: Cyprus, Spain, Croatia, the UK and Belgium.
[67] Based on the results of the surveys.
[68] Based on the data from France, Denmark, Cyprus, Sweden, Spain, Germany, Croatia, Malta, Latvia, the Netherlands, the UK and Belgium.
[69] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
				Only 17% of the products would apply for UA.					
Chrysanthemum cinerariaefolium	18	The available data shows that around 300 BPs containing chrysanthemum cinerariaefolium are currently on the market[70]	4 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[71]	Around 70% would choose for BPF.	0	0	0
Margosa extract	19	The available data shows that around 1400 BPs containing margosa extract are currently on the market[72]	9 out of 19 markets	In our survey none of the respondents expressed interest in UA for their products falling under PT19.	30%[73]	Around 70% would choose for BPF.	0	1	1+1 family
Prallethrin	18	The available data shows that around 350 BPs containing Prallethrin are currently on the market[74]	12 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[75]		0	0	0

[70] Based on the data from France, Germany, Croatia and Belgium.
[71] Based on the results of the surveys.
[72] Based on the data from France, Cyprus, Spain, Germany, Croatia, Latvia, Estonia, the UK and Belgium.
[73] Based on the results of the surveys.
[74] Based on data from Belgium, the UK, Netherlands, Estonia, Latvia, Malta, Slovenia, Croatia, Germany, Spain, Sweden and Cyprus.
[75] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
Silicium dioxide (Kieselguhr)	18	The available data shows that around 200 BPS containing silicium dioxide are currently on the market[76]	7 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[77]	Around 70% would choose for BPF.	0	0	0
Silicon dioxide (as a nanomaterial formed by aggregates and agglomerates) (Degussa/Evonik)	18	Only in in the UK 5 BPs containing silicon dioxide are registered.	1 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[78]	Around 70% would choose for BPF.	0	0	0
Ethanol	1, 2, 4	The available data shows that around 3000 BPS containing ethanol are currently on the market[79]	11 out of 19 markets	For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	25%[80]	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	2+6 families	3+12 families	6+24 families

[76] Based on the data from Belgium, Latvia, Slovenia, Croatia, Germany, Spain and France.
[77] Based on the results of the surveys.
[78] Based on the results of the surveys.
[79] Based on the data from Belgium, the Netherlands, Estonia, Latvia, Malta, Slovenia, Croatia, Germany, Portugal, Cyprus and France.
[80] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
DPAB (polymeric betain)	8	It is unlikely that ECHA will receive any submissions for Union Authorisations for BPs containing this AS as the phasing in approach only makes UA possible for PT 8 in 2020. Industry has clearly indicated the importance of the duration and certainty of the outcome of the authorisation process. Therefore, we have taken the conservative assumption that for products containing this AS and falling under PT 8 no submissions will be made. This does not imply that the option for provisional union authorisation will not be used at all. Yet based on the available information at this time, industry does not express any interest. Additionally, products containing this active were only found in Germany.							
Esfenvalerate	18	The available data shows 17 BPs which are currently registered in France, Spain, Germany and Croatia.	4 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[81]	Around 70% would choose for BPF.	0	0	0
Hydrogen peroxide	11, 12	It is unlikely that ECHA will receive any submissions for Union Authorisations for BPs containing this AS as the phasing in approach only makes UA possible for PT 11 and 12 in 2020. Industry has clearly indicated the importance of the duration and certainty of the outcome of the authorisation process. Therefore, we have taken the conservative assumption that for products containing this AS and falling under PT 11 and/or 12 no submissions will be made. This does not imply that the option for provisional union authorisation will not be used at all. Yet based on the available information at this time, industry does not express any interest.							
Chlorfenapyr	18	The available data shows that currently 17 BPs containing chlorfenapyr are registered in Germany, Croatia, Slovenia and Latvia.	4 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[82]	Around 70% would choose for BPF.	0	0	0
Imiprothrin	18	The data available shows that there are currently around 60 BPs	9 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low	40%[84]	Around 70% would choose for BPF.	0	0	0

[81] Based on the results of the surveys.
[82] Based on the results of the surveys.
[84] Based on the results of the surveys.

Active substances with deadline in 2018	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2018		
		containing Imiprothrin are on the market[83].		interest in UA for products falling under this PT. Only 17% of the products would apply for UA.					
d-Tetramethrin	18	The data available shows that there are currently around 350 BPs containing d-Tetramethrin are on the market[85].	9 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[86]	Around 70% would choose for BPF.	0	0	0
Tetramethrin	18	The data available shows that there are currently around 1500 BPs containing Tetramethrin are on the market[87].	12 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[88]	Around 70% would choose for BPF.	1 family	1+1 family	2+2 families
MIT	11, 12	It is unlikely that ECHA will receive any submissions for Union Authorisations for BPs containing this AS as the phasing in approach only makes UA possible for PT 11 and 12 in 2020. Industry has clearly indicated the importance of the duration and certainty of the outcome of the authorisation process. Therefore, we have taken the conservative assumption that for products containing this AS and falling under PT 11 and/or 12 no submissions will be made. This does not imply that the option for provisional union authorisation will not be used at all. Yet based on the available information at this time, industry does not express any interest.							

[83] Based on the data from Malta, Latvia, the UK, Spain, Cyprus, Slovenia, Croatia, Germany and Sweden.
[85] Based on the data from Cyprus, Portugal, Spain, Germany, Croatia, Slovenia, Latvia, Estonia and the UK.
[86] Based on the results of the surveys
[87] Based on the data from France, Cyprus, Finland, Spain, Germany, Croatia, Slovenia, Malta, Latvia, Estonia, the Netherlands and the UK.
[88] Based on the results of the surveys.

Estimates for the year 2019

Table 0-4 Argumentation for estimated no. of submissions for UA based on the progress of the Review Programme in 2019

Active substances with deadline in 2019	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2019		
Esbiothrin 18	18	The data available shows that there are currently around 200 BPs containing esbiothrin are on the market[89]	12 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[90]	Around 70% would choose for BPF.	0	1 family	1 + 1 family
d-Allethrin 18	18	The data available shows that there are currently around 260 BPs containing d-allethrin are on the market[91]	11 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[92]	Around 70% would choose for BPF.	0	1 family	1 + 1 family
Lavender 19	19	The data available shows that there are currently around 700 BPs containing lavender are on the market[93]	7 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT.	30%[94]	Around 70% would choose for BPF.	0	0	0

[89] Based on the data from France, Denmark, Finland, Sweden, Spain, Germany, Malta, Croatia, Slovenia, Latvia and Estonia.
[90] Based on the results of the surveys.
[91] Based on the data from France, Denmark, Finland, Sweden, Spain, Germany, Croatia, Slovenia, Latvia, Estonia and the UK.
[92] Based on the results of the surveys.
[93] Based on the data from Estonia, Latvia, Slovenia, Germany, Spain, Cyprus and France.
[94] Based on the results of the surveys

Active substances with deadline in 2019	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2019		
				Only 17% of the products would apply for UA.					
20 AS	3			For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.		A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	2 + 2 families	5 + 5 families	8 + 8 families
20 AS	4			For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.		A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	2 + 2 families	5 + 5 families	10 + 10 families
10 AS	5			For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.		A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	1	2 +1 family	5 + 4 families

Active substances with deadline in 2019	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2019		
6 AS	1			For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.		A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	2 families	1+3 families	5+7 families
8 AS	2			For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.		A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	2 + 2 families	5 + 5 families	10+10 families

Estimates for the year 2020

Table 0-5 Argumentation for estimated no. of submissions for UA based on the progress of the Review Programme in 2020

Active substances with deadline in 2020	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2020		
Cyphenothrin PT18	18	The data available shows that there are currently around 220 BPs containing cyphenothrin are on the market[95]	5 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[96]	Around 70% would choose for BPF.	0	0	0
Geraniol PT18	18,19	The data available shows that there are currently around 1400 BPs containing cyphenothrin are on the market[97]	11 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only	40%[98]	Around 70% would choose for BPF.	1 family	1+1 family	2+2 families

[95] Based on the data from Spain, Germany, Croatia, Malta and the UK
[96] Based on the results of the surveys
[97] Based on the data from France, Cyprus, Portugal, Finland, Spain, Croatia, Slovenia, Malta, Latvia, the UK and Belgium
[98] Based on the results of the surveys

Active substances with deadline in 2020	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2020		
				17% of the products would apply for UA.					
Sodium cacodylate PT18	18	The available data shows that there are only 9 BPs currently registered on the market in Germany.	1 out of 19 markets	Both in our survey and the AISE/EBPF survey the industry reported very low interest in UA for products falling under this PT. Only 17% of the products would apply for UA.	40%[99]	Around 70% would choose for BPF.	0	0	0
8 AS	3			For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	15%	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	1 family	2 + 2 families	5 + 4 families

[99] Based on the results of the surveys.

Active substances with deadline in 2020	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2020		
15 AS	4			For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	40%	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	1 + 1 families	4 + 4 families	7 + 8 families
2	5			For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	20%	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	1	1	2 + 2 families
5	1			For all PTs falling under main group 1, UA is	25%	A high percentage of products will be	2 families	3 families	5+7 families

Active substances with deadline in 2020	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2020		
				perceived as a valid alternative to NA+MR.		placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.			
25	2			For all PTs falling under main group 1, UA is perceived as a valid alternative to NA+MR.	25%	A high percentage of products will be placed on the market under BPFs rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.	6 + 6 families	15 +15 families	20 + 25 families
5	6				30%	A high percentage of products will be placed on the market under BPFs	4	5	6 + 1 family

Active substances with deadline in 2020	PTs	Results from MSCA data on registered BPs	No. of markets the product is on according to the MSCA data	Results from our survey and AISE/EBPF survey on appropriateness of the PT the AS falls under for UA	Drop out rate based on surveys	Ratio BP/BPF based on surveys	Estimates 2020		
						rather than as separate products. According to the AISE/EBPF survey 60% of dossiers will be BPF.			

Annex 3: overview of the current fees for biocides authorisation

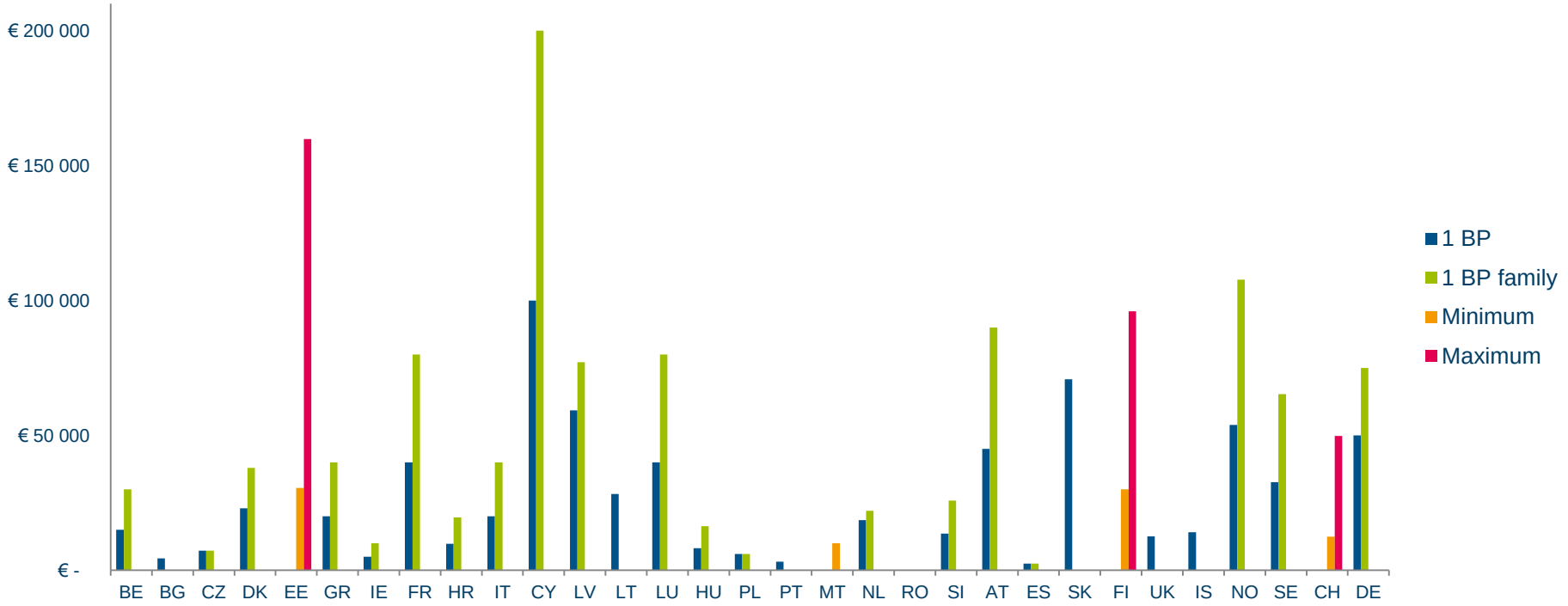
Table 0-1. Overview of current fee levels for National Authorisation and Union Authorisation of BP and BPF

MS	BP	BPF	MR BP	MR BPF	SME RED?	Annual fee
AT	€ 45.000,00	€ 90.000,00	€ 7.700,00	€ 15.400,00	No	€ 500 per BP and € 1000 per BPF
BE	€ 15.000,00	€ 30.000,00	€ 1.500,00	€ 3.000,00	Yes, SMEs will only pay € 11,500 for BP and € 22.500 for BPF authorisation	€ 300
BG	€ 4.320,50		€ 1.457,20		No	
HR	€ 9.784,70	€ 19.569,00	€ 1.696,00	€ 3.000,70	No	
CY	€ 100.000,00	€ 200.000,00	€ 500,00	€ 1.000,00	No	
CZ	€ 7.212,70	€ 7.212,70	€ 1.442,50		No	
DK	€ 22.965,40	€ 37.872,70	€ 10.139,70	€ 15.578,80	No	
EE	€ 56.780,00	€ 303.825,00	€ 1.375,00	€ 1.375,00	No	
FI	€ 96.000,00	€ 192.000,00	€ 12.000,00		No	
FR	€ 40.000,00	€ 80.000,00	€ 15.000,00	€ 30.000,00	No	
DE	€ 50.000,00	€ 75.000,00	€ 15.500,00	€ 23.300,00	Yes, instalments	
EL	€ 20.000,00	€ 40.000,00	€ 2.500,00	€ 5.000,00	No	
HU	€ 1.626,60	€ 16.265,50	€ 1.626,60	€ 3.253,00	No	
IE	€ 5.000,00	€ 10.000,00	€ 2.500,00	€ 225,00	No	
IT	€ 20.000,00	€ 40.000,00	€ 750,00	€ 5.000,00	Yes, 60% (medium) -40% (small) - 20% (micro)	
LV	€ 59.216,60	€ 77.048,20	€ 2.752,20		No	
LT	€ 28.256,80	€ 28.256,80	€ 3.096,90		No	
LU	€ 40.000,00	€ 80.000,00	€ 400,00	€ 800,00	Yes, 60% (medium) -40% (small) - 20% (micro)	
MT	€ 10.000,00		€ 350,00		No	

NL[100]	€ 18.500,00	€ 22.000,00			No	€ 1.195
PL	€ 5.957,10	€ 5.957,10	€ 1.477,90	€ 1.477,90	No	
PT	€ 3.078,00		€ 1.539,00		No	
RO	-	-	-	-	-	-
SK	€ 70.750,00		€ 7.500,00	€ 9.750,00	No	Between €300 - €750
SL	€ 13.500,00	€ 25.800,00	€ 2.500,00	€ 3.700,00	No	
ES	€ 2.436,90	€ 2.436,90	€ 1.160,40	€ 1.160,40	No	
SE	€ 32.619,70	€ 65.239,40	€ 13.047,90	€ 26.095,80	Yes, instalments	218-38097,7
UK	€ 12.495,20		€ 5.013,40		No	Yes, not specified
TOTAL			€ 114.524,70	€ 149.116,60		
EU[101]	€ 40.000 – 80.000	€ 150.000	-	-	Yes, 60% (medium) -40% (small) - 20% (micro)	Not yet, national annual fees might be implied

[100] For a comparative assessment, € 12.500 extra is invoiced
[101] For a comparative assessment € 40.000 (BP) or €60.000 (BPF) is invoiced

Figure 0-1. Overview of MS fees for product authorisation



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