



EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate A – Green Economy
ENV.A.3 - Chemicals

CA-Nov14-Doc.7.2

58th meeting of representatives of Members States Competent Authorities for the implementation of Regulation 528/2012 concerning the making available on the market and use of biocidal products

Report on the fees payable to Members States Competent Authorities pursuant to Article 80(2) of the Biocidal Product Regulation

ABBREVIATIONS

MS: MEMBER STATES

ECHA: EUROPEAN CHEMICALS AGENCY

BPR: BIOCIDAL PRODUCT REGULATION

BP: BIOCIDAL PRODUCT

CA: COMPETENT AUTHORITIES

PT: PRODUCT TYPE

AS: ACTIVE SUBSTANCE

SME: SMALL AND MEDIUM-SIZED ENTERPRISE

1. INTRODUCTION

1.1. Contextual and legislative background

Regulation (EU) No 528/2012 of 22 May 2012 concerning the making available on the market and use of biocidal products (hereafter the Biocidal Product Regulation- BPR) requires active substances present in biocidal products to be approved at Union level and subsequently authorised as a biocidal product at Union or Member State (MS) level before being made available on the market.

Besides provisions on fees payable to the European Chemicals Agency (ECHA), which are detailed in Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013, Article 80(2) of the BPR requires each MS to set fee structures and relative amounts payable to their Competent Authorities (CA) for the evaluation and authorisation procedures of active substances (AS) and biocidal products (BP) for which they could be evaluating CA under the BPR.

MS are indeed entitled to directly charge applicants fees for the evaluation of applications. Accordingly, MSs are expected to establish how these fees will be organised in detail (amount, timing and sequence of payment, options for refund etc).

In this context, diverging approaches between MSs in the structure and amount of fees payable to their CA may be expected. In view of this, and based on Article 80(2) and on the principles of Article 80(3) of the BPR, the European Commission (COM) has issued a guidance document containing recommendations for MS' fee structures and related procedures with a view to harmonising the latter (cf. CA-Dec12-Doc.5.1.b - Final) and avoiding gaps in national methods and/or fee levels.

1.2. Objectives of the report

The objective of this report is first to review the implementation of Article 80(2) of the BPR based on the fee-related legislative provisions currently in force in MS. The report thus provides an overview of MS' efforts to respect and put BPR provisions into practice, notably as regards the annual fee for the future self-financing of CA and the measures supporting Small and Medium-Sized Enterprises (SMEs). The underlying goal is also to determine to what extent MSs followed recommendations provided in the guidance document mentioned above (CA-Dec12-Doc.5.1.b - Final), in particular with regard to the proposed fee structure. In this respect, input from CA was highly helpful.

Secondly, the aim is to draw a comparative analysis of the relative costs of AS evaluation, BP authorisation, BP mutual recognition and annual fee in the EU MS, EEA countries and Switzerland for specific typical cases (defined in section 1.4). This is done by analysing the respective procedures and fee structures established in each of the respondent countries, and by highlighting potential divergences and similarities.

1.3 Areas of focus

The four following regulatory procedures required for the making available on the market of a BP have been singled out to compare the overall fee structures and levels in the EU MS, EEA countries and Switzerland:

- Fees for the evaluation of AS per Product Type (PT) and per additional PT;
- Fees for the authorisation of a BP and of a BP family;
- Fees for the mutual recognition of an authorisation for a BP and for a BP family;
- The annual fee (optional);
- Existing measures supporting SMEs in this process.

1.4 Method and limits of analysis

For the purpose of this report, the following typical cases were taken into account:

- For active substance approval: a chemical AS for one PT (information on the fee per additional PT is also provided);
- For biocidal product authorisation: a BP containing a single chemical AS for a single PT (information on the fee per BP family is also provided);
- For mutual recognition: a BP containing a single chemical AS for a single PT (information on the fee per BP family is also provided).

In addition to these typical cases, two qualitative features were considered:

- The potential annual fee paid by a single company to register a single BP or a BP family and/or to financially support the activities of MS' CA.
- The potential measures chosen by MSs to support SMEs in this process, i.e. mostly payment facilities and reduced fees.

This approach is used in order to highlight **average indicative fee amounts**. This means that **these amounts do not include any top-up fee that a wide majority of MSs apply to their basic fee** (see section 2.1). Thus, figures for AS approval, BP authorisation and mutual recognition are likely to be significantly higher. Depending on each individual case at hand, a scenario with a minimum and maximum fee to be paid could be drawn.

Moreover, specific procedures such as modification or renewal of authorisations, etc. are excluded from the analysis.

Finally, in some MS, complete and updated data was not always available where the relevant legislation was currently under review.

2. COMPARATIVE EVALUATION OF LEGISLATIVE FRAMEWORK AND ORGANISATIONAL FEE STRUCTURE IN EU MEMBER STATES, EEA COUNTRIES AND SWITZERLAND

This section aims at comparing the approach used by MSs to set general fee levels, potentially an annual fee, and specific measures to support their SMEs in this context.

2.1. General organisation of fee structure and payment in MSs

Evidently, MSs' organisational structures for BP fee levy do not always strictly follow the options of the guidance document in a clear-cut way. On the contrary, MSs' method and organisation entail many subtleties, as well as specific measures linked to their budgetary and organisational specificities. Therefore, several MSs use a mix of different options to organise their fee structure and levels.

This is summarised in the table below.

Respondents	Option A	Option B	Option C	Option D	Legislation in process of adoption	Legislation currently under review
Member States+ EEA countries and CH	EE, FI, CH	EE, NL, UK, IS	BE, DK, GR, IE, FR, HR, IT, LV, LU, HU, MT, SI, AT, NO, SE, NL, PL, ES, SK, PT, LT, DE	UK, FI	BG, EE, GR, IT, AT, LU, HU, RO, ES	NL, PL, UK, CZ, PT

2.1.1 A large majority of MSs opted for a flat fee with top-up and additional fees (option C) (=22/28)

Following the table above, it appears that a large majority of MSs (22= BE, DK, GR, IE, FR, HR, IT, LV, LU, HU, MT, SI, AT, NO, SE, NL, PL, ES, SK, PT, LT, DE) have chosen to follow option C of the guidance document (CA-Dec12-Doc.5.1.b –Final). This group thus established a flat fee which applies to all applicants and represents the average costs of assessing a specific type of application. In most of these MS, top-up fees are added to this flat fee.

2.1.2 A minority of MSs opted for a proportionate fee (options A, B and D) (=6/28)

Only 6 MSs (EE, FI, CH, NL, UK, IS) chose option A (EE, FI, CH), option B (EE, NL, UK, IS), or option D (UK, FI) of the guidance document- or a mix of both, illustrated un the table above-, which implies collecting a fee at the start of the procedure to which top-fees fees and potential additional fees can be added before the end of the procedure. A maximum fee is also often established.

UK and FI stand out as having set the most tailored approach reflecting the administrative burden of evaluating applications. This implies collecting different fees, for different purposes and at different times during the procedure (option D) - in both cases with hourly/daily work rates.

Furthermore, it is relevant to point out that in two of the MSs who have chosen option A or D, a refund system is in place when the fee paid exceeds the final costs of handling specific applications (EE, UK).

Two other countries have also ensured such a possibility (NL, IS). This corresponds to option B of the guidance document.

2.1.3 A large group of MSs are in the process of adoption/review of relevant legislation (14/28)

In 9 MSs (BG, EE, GR, IT, AT, LU, HU, RO, ES), the national legislation implementing the BPR as regards fee levy for BPs was still in process of adoption at the time of study. However, the scheme for this purpose had been already defined in most of these MSs .

Moreover, 5 MSs are in the process of reviewing their current legislation (NL, PL, UK, CZ, PT).

2.2. Annual fee

As regards the establishment of an annual fee for the registration of authorised BPs, only 9 MSs (BE, IE, IT, AT, SK, NO, NL, SE, UK) had set such a fee at the moment of writing; whilst 20 of the respondents had not. Except for NL and SE, most of the existing annual fees are in a 100-500€ range.

The annual fee was suggested in the BPR as a source of revenue to finance overhead expenses under CA' BPR-related activities with a longer-term view of self-financing MSs ' BP fee system, on the same model as the fees payable to the ECHA.

The MSs who have established an annual fee are listed in the table below.

Member States	Nature and purpose of annual fee
BE	<p>The Belgian annual fee is payable to the "Fonds budgétaire des matières premières et des produits" for all AS or BP who received notification, approval of notification, authorisation or mutual recognition. The amount is then calculated based on the quantity of BP placed on the Belgian market (expressed in kg, l or %) and the number of hazard-based points corresponding to each BP.</p> <p>The annual fee compensates for the human resources costs of internal evaluation for BP. However, such costs are already taken into account and are reflected in the flat fee for AS evaluation.</p>
IE	<p>The Irish annual fee is called Annual Registration Fee (ARF) and distinguishes between professional products and non-professional products. A higher fee is also due when "re-instating product on the register/late ARF", with the same distinction between professional and non-professional product.</p> <p>For each of these annual fees, €25 needs to be transferred to the Poisons Information Centre to "cover the cost of maintaining the poisons database". There is also a fee to obtain a Certificate of Inclusion in the Register. No detail provided on the exact purpose of the fee.</p>
IT	Simple flat annual fee for the registration of a single BP according to article 80 of the BPR. No detail provided on the exact purpose of the fee.
NL	Simple flat annual fee for the placing on the market of BPs. No detail provided on the exact purpose of the fee.
AT	Simple flat annual fee for the registration of a single BP and BP families per calendar year. No detail provided on the exact purpose of the fee.

SK	Different annual fees: for the inclusion of a BP in the register of BPs placed on the Slovak market, for a single BP placed on the market based on application for national authorisation or of Union authorisation where SK CA were the evaluating authority, for a single BP placed on the market based on application for mutual recognition in sequence or in parallel, for a BP placed on the market based on a specific regulation. No detail provided on the exact purpose of the fee.
NO	A basic annual fee applies to registered BP and BP families. Additionally, a variable annual fee applies based on the sales volume (reported to the National Product Register for the preceding year) and the hazardous properties of the BP (i.e. the classification and labelling of the BP). The details on the purpose of the annual fee are stated in paragraph 4 of the Norwegian biocide regulation implementing the BPR. The annual fee should cover the actual expenses of the services provided by the authorities (all expenses, including enforcement, which are not directly connected to the handling of application for product authorisation).
SE	The annual fee is based on the amount of BPs sold the year before, e.g 2013 is used as reference year for the 2014 annual fee. For 2015, the Swedish annual fee will correspond to 4% of the sales value in 2014 for each authorised BP with a corresponding minimum and maximum fee. The purpose of the fee is to finance enforcement and information to applying companies and to partly finance the national data base for biocidal products (the annual fee is applicable also for biocidal products that are authorised under the existing national practice during the transitional period).
UK	A "General Industry Charge" (GIC), which is charged under the Biocidal Products (Fees and Charges) Regulations 2013, applies industry-wide annually to cover the costs for on-going general activity carried out by UK CA in operating the biocides regulatory framework

2.3. Support measures for SMEs

Similarly to the annual fee, only 7 MSs (BE, IE, IT, LU, AT, SE, DE) have planned measures to support their SMEs in this process; whilst 21 of the respondents had not.

Among such measures, 3 out of the 7 MSs (BE, IT, LU) provide reduced rates (e.g. percentage of initial fee) for SMEs according to their respective size (micro, small, medium).3 MSs (SE, AT, DE) have established special payment instalments for SMEs to split the different amounts in different phases¹.

This is summarised in the table below.

Member States	Existing measures supporting SMEs
BE	Reduced costs for evaluation of active substances (-40%) and authorisation procedure of BPs (-40%) except for modifications/prolongation/renewal under different procedures as well as for overhead expenses covering administrative costs.
IT	Fee reductions for evaluation and authorisation procedures: 60% of standard fee for micro companies, 40% for small, 20% for medium sized companies.
LU	Applicable reduction rates for evaluation and authorisation procedures : medium companies (20% of basic fee for evaluation of AS and 10% for BP authorisation), small (40% of basic fee for evaluation of AS and 20% for BP authorisation), micro (60% of basic fee for evaluation of AS and 30% for BP authorisation).
AT	Instalments for up to 5 years if the fees are above 50.000€.
SE	Provisions include a possibility of splitting payments into several instalments and phases, according to Chapter 9 Section 1 in the Ordinance (2013:63) on Fees for Pesticides.
DE	Splitting payments into several instalments is negotiable on a case-by-case basis.

¹ Some MSs such as IE have chosen to provide SMEs with workshops and specific meetings in order to advise the latter on technical issues of BP authorisation and more generally on the financial costs of the BPR.

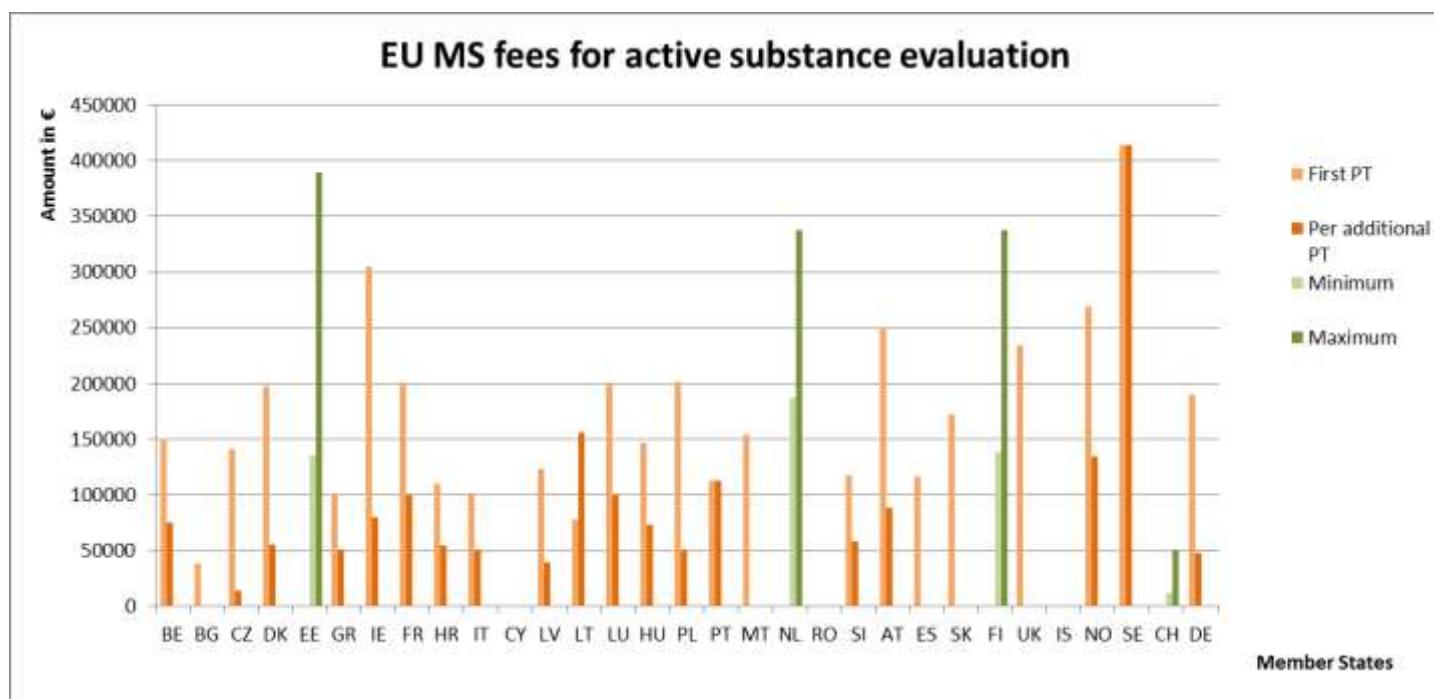
3. COMPARATIVE EVALUATION OF THE LEVELS OF FEES PAYABLE TO COMPETENT AUTHORITIES

This section aims at emphasising the divergences of fee levels among the countries under study for the four regulatory procedures detailed in section 1.4. The tables below illustrate the different levels of fees payable in the MSs, EEA countries and Switzerland for the evaluation of AS, the authorisation of BPs, their mutual recognition, the potential adoption of an annual fee, and the potential establishment of measures for SMEs. The minimum and maximum fees established in some MSs correspond to the fee for procedures related to a single PT or a single BP.

3.1. Fee for AS approval – articles 4-11 of the BPR

One major comment is that the fee for the AS evaluation of one product type (PT) varies considerably from one MS to another, ranging from less than 150.000€ (BG, BE, GR, HR, IT, LV, LT, HU, SI, ES, CZ, FI, PT) to a range of 150.000-200.000€ (FR, LU, MT, DE, SK, DK). Lastly, in some MS, this fee is clearly above 200.000€ (IE, AT, NO, SE, UK, PL, NL²). However, approximately one third of the respondents (12 MS) did choose to set this fee below 150.000€.

The established fees for the evaluation of additional PTs (when this data was available) are in most MSs lower than the fee for the evaluation of a first PT (BE, CZ, DK, GR, IE, FR, HR, IT, LV, LU, HU, PL, SI, AT, NO, DE, FI), or equal to it (LT, SE, PT), except for LT (where the fee for one PT is multiplied according to the number of additional PTs). In 5 MSs (BG, ES, SK, MT, UK), the amount of this fee was not specified.

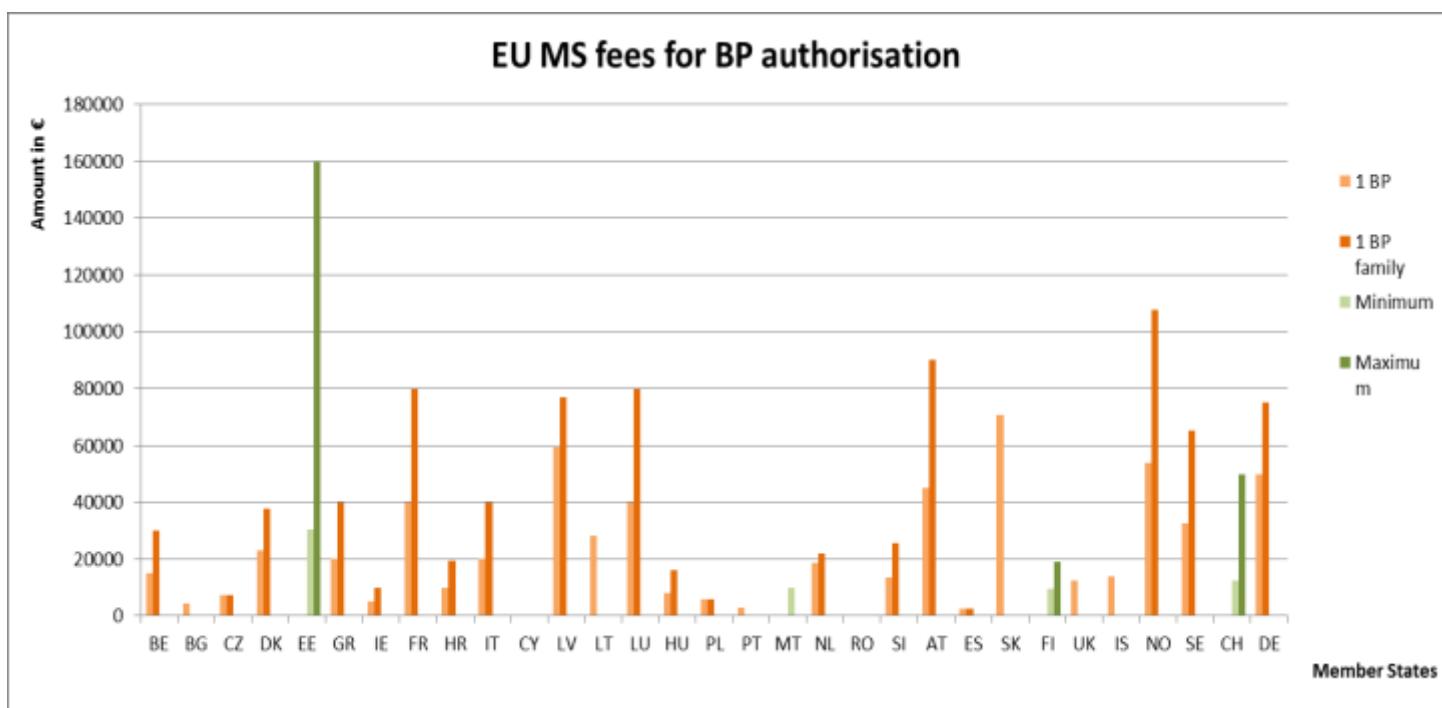


² The initial fee can however be higher as the NL do not calculate per (additional) PT but according to the complexity of the dossier.

3.2. Fee for BP authorisation – articles 29-31 of the BPR

As regards the fee for the authorisation of a BP, it appears that more than half of the MSs (17) have established the latter below 20.000€ (BE, BG, GR, IE, HR, IT, HU, PL, NL, SI, ES, SK, IS, CZ, UK, FI, PT), whilst 8 have set it above 20.000€ (DK, FR, LV, LT, LU, AT, NO, SE), among which 5 have set it above 40.000€ (LV, AT, NO, DE, SK).

The established fees for the authorisation of a BP family (when this data was available) are in most MSs higher than the fee for the authorisation of a single BP (BE, DK, GR, IE, HR, LV, LU, HU, NL, SI, AT, NO, SE, DE, IT, FI, FR) or equal to it (CZ, ES, PL). In 6 MSs (BG, SK, IS, UK, LT, PT), the amount of this fee was not specified.

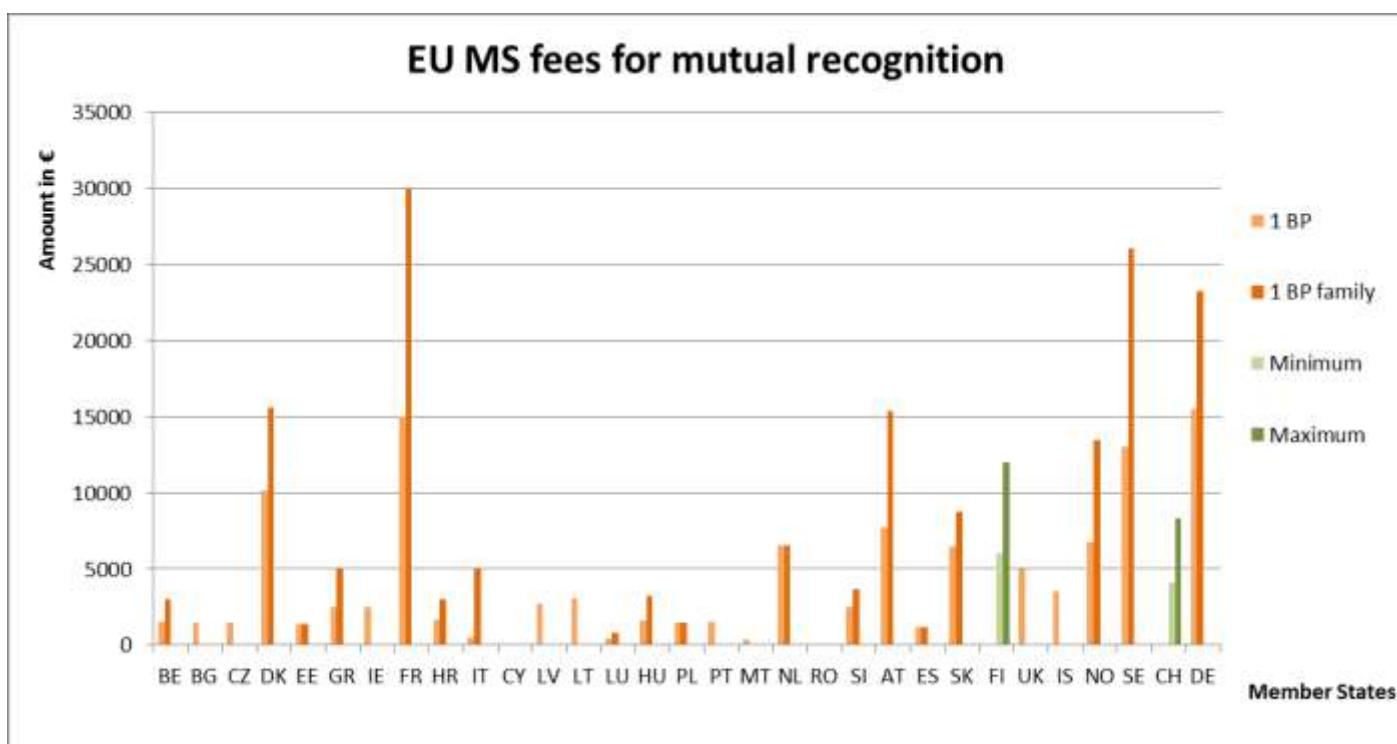


3.3. Fee for mutual recognition of BP authorisations –articles 32-40 of the BPR

In 10 MS, the fee to obtain a mutual recognition of a BP authorisation exceeds 5000€ (DK, FR, NL, AT, FI, NO, SE, DE, SK, UK), half of which MSs have set this fee above 10.000€ (DK, FR, SE, DE).

However, in 18 MSs (BE, BG, CZ, EE, GR, IE, HR, IT, LV, LT, LU, HU, PL, MT, SI, ES, IS, PT), the mutual recognition fee for a single BP is situated below 5000€, as is the average for all respondents (approximately 4000€).

The established fees for the mutual recognition of a BP family (when this data was available) was in most MSs higher than the fee for the mutual recognition of a single BP (BE, DK, GR, HR, LU, HU, SI, AT, SK, NO, SE, DE, FR) or equal to it (EE, NL, ES, PL, FI). In 8 MSs (BG, CZ, IE, LV, MT, IS, UK, LT), this fee was not specified.



3.4. Annual fee – article 80 of the BPR

See section 2.2.

Most MSs who have established an annual fee have chosen to set it below 500€ (BE, IE, IT, AT, NO, SK) at an average of 280 EUR (i.e. 1960 EUR for these 6 countries). NL stands out with a fee above 1000 EUR, at 1200 EUR along with Se whose annual fee varies between 300 and 30.000 EUR depending on the value of sales. UK also has a general industry charge, which was however difficult to estimate and is therefore not available.

Details are provided in the tables in Annex 1.

4. FINAL COMMENTS

On the basis of this study, bearing in mind the advantages of resorting to a Union authorisation which opens access to the entire Union market at once instead of having to undergo the more complex mutual recognition process, it appears that the costs of resorting to national authorisations via mutual recognition of BPs is not significantly different from those of applying for Union authorisation.

Regarding annual fees, similar conclusions can be drawn. However, in the case of annual fees, the issue identified through communication from stakeholders is the concern that, for products authorised by the Union, companies might be forced to pay both the ECHA and MS' annual fees, which would create a serious disincentive of opting for a Union authorisation.

This bears considerable importance in the context of the COM review of Regulation 524/2012, notably with regard to the level of fees payable to the ECHA.

**ANNEX 1: LEGISLATIVE FRAMEWORK, OVERALL STRUCTURE AND FEE LEVELS IN MS,
EEA COUNTRIES, AND SWITZERLAND**

AUSTRIA	
Link to national legislation	https://www.wko.at/Content.Node/Interessenvertretung/Umwelt-und-Energie/-Positionen-/BiozidprodukteG2013_105-I.pdf
Evaluation of active substances	$32.000+218.000=250.000\text{€}$ + additional fees for 1 PT , 88.000€ per additional PT
Authorisation of BPs	$39.400+5.600=45.000\text{€}$ for 1 BP, $11.300+78.700=90.000\text{€}$ for 1 BP family
Mutual recognition of authorisations	7.700€ for 1 BP, 15.400€ for 1 BP family
Annual fee	$\text{€ } 500$ for 1 authorised BP, 1000€ for 1 authorised BP family per calendar year
Measures in favour of SMEs	Instalments up to five years if the fees are above $\text{€ } 50.000$.
Comments	Option C of the guidance document. Top-up and additional fees apply. Austria has planned some enforcement measures such as penalties if these provisions are not respected. Law should be confirmed at the end of 10/2014.

BELGIUM	
Link to legislation	http://www.ejustice.just.fgov.be/cgi_loi/change_lg.pl?language=fr&la=F&cn=2014080414&table_name=loi
Evaluation of active substances	150.000€ for 1 PT (SMEs= 90.000€), 75.000€ per additional PT (SMEs= 45.000€)
Authorisation of BPs	10.000 € for 1 BP (SMEs= 7.500€) until 31/12/2014, 15.000€ as of 01/01/2015 (SMEs= 11.000€), 30.000€ for 1 BP family (SMEs= 22.500€)
Mutual recognition of authorisations (for 1 BP and for a BP family)	1.500 € for 1 BP, 3.000€ for 1 BP family
Annual fee	Minimum of 300€ (calculation based on risk phase and quantity placed on the market)
Measures in favour of SMEs	Reduced costs for evaluation of active substances (-40%) and authorisation procedure of BPs (-40%) except for modifications/prolongation/renewal under different procedures and overhead expenses (administrative costs)
Comments	Option C of guidance document: flat fee and top-up+ additional fees for all applicants with reduced costs for SMEs.

BULGARIA	
Link to legislation	Hyperlink?
Evaluation of active substances	75.150 BGN=38424.17€ ³ for 1 PT, fee per additional PT not envisaged yet
Authorisation of BPs	8.450 BGN=4320.5€ for 1 BP, fee for 1 BP family not envisaged yet
Mutual recognition of authorisations	2.850 BGN=1457.2€, fee for 1 BP family not envisaged yet
Annual fee	No
Measures in favour of SMEs	No
Comments	Final fees should be obtained week 20/10- following which option from guidance document? Top-up and additional fees?

CROATIA	
Link to legislation	Hyperlink?
Evaluation of active substances	840.000 HRK=109589€ ⁴ for 1 PT, 420.000 HRK=54794.5€ per additional PT (chemical agent)
Authorisation of BPs	75.000 HRK=9784.7€ for 1 BP, 150.000 HRK=19569.5€ for a BP family
Mutual recognition of authorisations	13.000 HRK=1696€ for 1 BP, 23.000 HRK=3000.7€ for 1 BP family
Annual fee	No
Measures in favour of SMEs	No specific measures.
Comments	Option C of the guidance document with percentage of additional fees according to required work. Top-up and additional fees.

³ 1 EUR = 1.95590 BGN (20/10/2014)

⁴ 1 EUR = 7.66568 HRK (20/10/2014)

CYPRUS	
Link to legislation	
Evaluation of active substances	
Authorisation of BPs	
Mutual recognition of authorisations	
Annual fee	
Measures in favour of SMEs	
Comments	Top-up and additional fees?

CZECH REPUBLIC	
Link to legislation	Hyperlink?
Evaluation of active substances	3.900.000 CZK= 140.647€ ⁵ for 1 PT, 390.000 CZK= 14064.7€ per additional PT
Authorisation of BPs	200.000 CZK= 7212.7€ for 1 BP, 200.000 CZK= 7212.7€ for 1 BP family
Mutual recognition of authorisations	40.000 CZK= 1442.5€ for 1 BP? (not specified for 1 BP family)
Annual fee	No
Measures in favour of SMEs	No
Comments	Top-up and additional fees?

⁵ 1 EUR = 27.7687 CZK

DENMARK	
Link to legislation	https://www.retsinformation.dk/Forms/R0710.aspx?id=161415
Evaluation of active substances	DKK 1,468,000 = € 197,120. ³ for first PT, DKK 564,000 = € 55,732.9 for each additional PT
Authorisation of BPs	DKK 171,000 = € 22,965.4 per BP and PT, DKK 282,000 = € 37,872.7 for a BP family + additional fees
Mutual recognition of authorisations	DKK 75,500 = €10,139.7 per BP and PT, DKK 116,000 = € 15,578.8 for a BP family + additional fees
Annual fee	No
Measures in favour of SMEs	No specific measures.
Comments	Option C of guidance document= dynamic model of a basic fee that may be upgraded with possible overhead expenses (= additional fees classified from A type to E type). Top-up and additional fees.

ESTONIA	
Link to legislation	http://www.terviseamet.ee/kemikaaliohutus/biotsiid/biotsiidialane-seadusandlus.html
Evaluation of active substances	<ul style="list-style-type: none"> - Basic payment for 1 PT (state fee= 1.720+basic fee= 133.865): 135.585 € - Maximum payment for 1 PT (state fee=1.720+max fee= 387.945): 389.665 €
Authorisation of BPs	<ul style="list-style-type: none"> - Basic payment for 1 BP (state fee=1.635+basic fee= 28.865): 30.500 € - Basic payment for 1 BP family (state fee=1.635 +basic fee= 55.145): 56.780 € - Maximum payment for 1 BP (state fee=1.635+max fee=158170): 159.805 € - Maximum payment for 1 BP family (state fee=1.635 +basic fee= 302190): 303.825 €
Mutual recognition of authorisations	1.375€ for 1 BP, 1.375€ for 1 BP family
Annual fee	No
Measures in favour of SMEs	No
Comments	<p>Option A of the guidance document but without collection of overhead expenses (with possibility of refund like in Option B). The Estonian payment system consists of two parts: state fee (riigilõiv) and fee for evaluation (tasu). The state fee covers all activities before evaluation (administrative part) and it includes a completeness check (the state fee is fixed). The evaluation fee is flexible whereas the basic and maximum fees are set. Depending on the level of the complexity of evaluation, there is a possibility of refunding the amount paid in excess when the costs are lower, even for the basic fee.</p> <p>Law currently in process of adoption (see https://www.riigiteataja.ee/en/search).</p>

³ 1 EUR = 7.44723 DKK (20/10/2014)

FINLAND	
Link to legislation	http://www.tukes.fi/Tiedostot/Kemikaalituootteet/biosidit/Maksut/Fees_biocides2013.pdf
Evaluation of active substances	<ul style="list-style-type: none"> Basic fee for 1 PT=138.000€/maximum fee=338.000€ Basic fee per additional PT= 46.000€/maximum fee=69.000€
Authorisation of BPs	<ul style="list-style-type: none"> If assessed in conjunction with active substance evaluation: Basic fee= 9.600€/maximum fee= 19.200€ If assessed in no such conjunction: basic fee= 30.000/maximum fee= 96.000€ BP family= double fee
Mutual recognition of authorisations	<ul style="list-style-type: none"> Basic fee= 6.000€ Maximum fee=12.000€
Annual fee	No
Measures in favour of SMEs	No
Comments	Option A of the guidance document+ parts of option D (hourly fee)

FRANCE	
Link to legislation	http://www.legifrance.gouv.fr/jopdf/common/jo_pdf.jsp?numJO=0&dateJO=20140626&numTexte=7&pageDebut=10477&pageFin=10479
Evaluation of active substances	200.000€ for 1 PT, 100.000€ per additional PT
Authorisation of BPs	40.000€ for 1 BP, 80.000€ per additional type of BP
Mutual recognition of authorisations	15.000€ for 1 BP, 30.000€ per additional BP
Annual fee	No
Measures in favour of SMEs	No specific measures.
Comments	Option C of the guidance document. Top-up and additional fees.

GERMANY	
Link to legislation	http://www.reach-clp-biozid-helpdesk.de/de/Rechtstexte/RText-Biozide/RText-Biozide.html (Chemikalien-Kostenverordnung (ChemKostV))
Evaluation of active substances	189.800€ for 1 PT, 47.500€ for additional PT (with potential additional fees)
Authorisation of BPs	50.000€ for 1 BP, 75.000€ for 1 BP family 14.300€ for 1 BP, 19.600€ for 1 BP family if the product to be authorised is identical to the reference product evaluated during authorisation of the AS. + Top-up fees may apply*
Mutual recognition of authorisations	15.500€ for 1 BP, 23.300€ for 1 BP family
Annual fee	No.
Measures in favour of SMEs	Possibility to split payments into multiple instalments.
Comments	Option C of the guidance document. * Top-up fees for each additional active substance, product type or user category; for comparative assessment and assistance during the establishment of maximum residue limits

GREECE	
Link to legislation	Not published yet. The fees summarised below are not legally adopted yet since they are still under publication.
Evaluation of active substances	100.000€ for 1 PT, 50.000€ per additional PT
Authorisation of BPs	20.000€ for 1 BP, 40.000 for 1 BP family
Mutual recognition of authorisations	2.500€ for 1 BP, 5.000€ for 1 BP family
Annual fee	No
Measures in favour of SMEs	No specific measures.
Comments	Option C of the guidance document. The fees are doubled in case of biocidal product families. Top-up and additional fees?

HUNGARY	
Link to legislation	Hyperlink?
Evaluation of active substances	45.000.000 FT=146389.1€ ⁷ for 1 PT, 22.500.000 FT=73194.5€ per additional PT
Authorisation of BPs	<ul style="list-style-type: none"> • 500.000 FT=1626.6€ for BP identical with one of the representative products assessed, • 2.500.000 FT=8132.7€ for BP not identical with one of the representative products assessed, • 5.000.000 FT=16265.5€ for 1 BP family
Mutual recognition of authorisations	500.000 FT=1626.6€ for 1 BP, 1.000.000 FT=3253.1€ for 1 BP family
Annual fee	No
Measures in favour of SMEs	No
Comments	Option C of the guidance document. Top-up fees. Law in process of adoption

⁷ 1 EUR = 306.685 HUF (20/10/2014)

IRELAND	
Link to legislation	http://www.irishstatutebook.ie/2013/en/si/0427.html http://www.pcs.agriculture.gov.ie/Docs/BiocidalProductfeesJanuary2014.pdf
Evaluation of active substances	305.000€ for 1 PT (pro rata), 80.000€ for additional PT
Authorisation of BPs	5.000€ for 1 BP, 10.000€ for 1 BP family
Mutual recognition of authorisations	2.500€ (not detailed if it's only for 1 BP but most likely it is)
Annual fee	225€ for professional product (non-professional products= 125€) Re-instating product on the Register/Late ARF (professional product) €425* Re-instating a product on the Register/Late ARF (non-professional product) €225* Certificate of Inclusion on the Register (Certificate of Free Sale) €150 * €25 will be transferred to the Poisons Information Centre to cover the cost of maintaining the poisons database.
Measures in favour of SMEs	No specific measures.
Comments	Option C of the guidance document. Application of identical fee for all applicants covering average costs of application assessment, including proportionate overhead expenses. Top-up and additional fees.

ITALY	
Link to legislation	Hyperlink?
Evaluation of active substances	100.000€ for 1 PT, 50.000€ per additional PT
Authorisation of BPs	20.000€ for 1 BP, 40.000€ for 1 BP family
Mutual recognition of authorisations	500/750? For 1 BP, 5.000€ for 1 BP family
Annual fee	200€ per BP (art 80 BPR)- in “other fees”
Measures in favour of SMEs	Fee reductions for evaluation and authorisation procedures: <ul style="list-style-type: none"> • Micro-enterprises pay 60% of the standard fee • Small enterprises pay 40% of the standard fee • Medium enterprises pay 20% of the standard fee
Comments	Option C of the guidance document. Top-up fees.

LATVIA	
Link to legislation	<u>http://m.likumi.lv/doc.php?id=259619</u> <u>http://www.meteo.lv/fs/CKFinderJava/userfiles/files/Fee%20for%20evaluation%281%29.pdf</u>
Evaluation of active substances	122.872€ for 1 PT, 38.931.14€ per additional PT
Authorisation of BPs	59216.6€ for 1 BP, 77048.2€ for 1 BP family
Mutual recognition of authorisations	2752.2€ (in sequence and in parallel)
Annual fee	No
Measures in favour of SMEs	No
Comments	Option C of the guidance document. Top-up fees.

LITHUANIA	
Link to national legislation	<u>https://www.e-tar.lt/portal/lt/legalAct/0f86f7c03e6511e498a79e861091cd92</u>
Evaluation of active substances	270 000 LTL (Point 4. 20.1)= 78197.4€ ⁸ for 1 PT/ 156394€ per additional PT (78197*2)
Authorisation of BPs	97 565 LTL (Point 4.20.1.1) =28256.8€ (no distinction with BP family)
Mutual recognition of authorisations	10 693 LTL (Point 4.20.1.3) =3096.9€ (no distinction with BP family)
Annual fee	No
Measures in favour of SMEs	No specific measures.
Comments	Additional fees apply.

⁸ 1 EUR = 3.45280 LTL (21/10/2014)

LUXEMBOURG	
Link to national legislation	http://www.chd.lu/wps/portal/public/RoleEtendu?action=doDocpaDetails&id=6689&back_to=/wps/portal/public/Abonnement#
Evaluation of active substances	200.000€ per PT, 100.000€ per additional PT (for chemical compound)
Authorisation of BPs	40.000€ for 1 BP, 80.000€ for 1 BP family
Mutual recognition of authorisations	400€ for 1 BP, 800€ for 1 BP family
Annual fee	No
Measures in favour of SMEs	Applicable reduction rates for evaluation and authorisation procedures: <ul style="list-style-type: none"> medium-sized company: 20% of the basic fee for the evaluation of active substance and 10 % of the fee for authorisation of BPs; small-sized company: 40% of the basic fee for the evaluation of active substance and 20% of the fee for authorisation of BPs; micro company: 60% of the basic fee for the evaluation of active substance and 30% of the fee for authorisation of BPs.
Comments	Option C of the guidance document. Additional fees proportional to the nature and scope of the procedure are established (top-up and additional fees), with corresponding reduced rates for SMEs. Provision allowing for overhead cost recovery is included. Law in process of adoption.

MALTA	
Link to legislation	http://mccaa.org.mt/en/fees
Evaluation of active substances	154.000 € per PT/per additional PT (not specified)
Authorisation of BPs	10.000€ minimum (maximum not specified)
Mutual recognition of authorisations	350€ (not specified)
Annual fee	No
Measures in favour of SMEs	No specific measures (small market).
Comments	Option C of the guidance document. Top-up and additional fees?

NETHERLANDS	
Link to legislation	http://ctgb.nl/docs/default-source/Tarieven-2014/tarievenbesluit-20ctgb-202014-20v3-0_en_defbk.pdf?sfvrsn=2
Evaluation of active substances	187 500 - 337 500 € - depending on the complexity of the dossier. - fees are advance payments, applicant will pay actual costs.
Authorisation of BPs	18.500 € for 1 BP, 22.000€ for 1 BP family - fees are advance payments, applicant will pay actual costs. - additional fee if product contains a candidate for substitution: comparative assessment= 12,500€.
Mutual recognition of authorisations	6.555 € (all-in-one tariff). No refunds in case of lower costs. Identical for 1 BP family.
Annual fee	1195 €
Measures in favour of SMEs	No
Comments	Option C of the guidance document. Top-up and additional fees. Refund system in place (refund or extra fee demanded if exceeding costs). NL considers switching to add-on fee system for biocidal products as of 2015 (board decision pending)- following option C of guidance document.

POLAND	
Link to legislation	http://en.urpl.gov.pl/article/legislation
Evaluation of active substances	850.000 PLN=200993.1€ ⁹ for 1 PT, 25% of evaluation fee per additional PT=212 500 PLN=50248.3€
Authorisation of BPs	24.000 PLN= 5905.1€ =cost for issuing authorisation, 24.000 PLN= 5905.1€ for 1 BP family
Mutual recognition of authorisations	6.250 PLN=1477.9 € (both in parallel and in sequence) for 1 BP, 6.250 PLN=1477.9 € for 1 BP family
Annual fee	No
Measures in favour of SMEs	No
Comments	Option C of the guidance document. Top-up and additional fees apply. Law will be changed beginning of 2015.

⁹ 1 EUR = 4.22595 PLN (24/10/2014)

PORUGAL

Link to legislation	<p>http://www.dgs.pt/pagina.aspx?f=1&lws=1&mcna=0&lnc=&mid=5005&codigoms=0&codigono=552055525579AAAAAAAAAAAA</p> <p>http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=198536&generico=17307&cboui=17307</p> <p>http://www.dgv.min-agricultura.pt/portal/page/portal/DGV/genericos?actualmenu=3665829&generico=3665830&cboui=3665830</p>
Evaluation of active substances	For a single PT: Request and validation – 10.260€ (under revision) Assesment – 102.600€ (under revision) Total= 112860€
Authorisation of BPs	For a single BP: Request and validation – 1.026€ (under revision) Assesment – 2.052€ (under revision) Total= 3078€
Mutual recognition of authorisations	For a single BP: 1.539€ (under revision) For a BP family: (under discussion for revision)
Annual fee	No (under revision)
Measures in favour of SMEs	No (under revision)
Comments	Top-up and additional fees. Legislation currently under review.

ROMANIA

Link to legislation	http://www.insp.gov.ro/images/documente/biocide/Ordin%20nr.%2010_2013.pdf
Evaluation of active substances	1.228 RON
Authorisation of BPs	1318.5 RON
Mutual recognition of authorisations	363 RON
Annual fee	
Measures in favour of SMEs	
Comments	Option C of the guidance document? Top-up fees. Point 1 in Appendix 1 or Point 1 in Appendix 2 correspond to fees for administrative procedures of the biocides unit.

SLOVAKIA	
Link to legislation	http://www.mhsr.sk/introduction/142469s : administrative fees regulated under Article II in Act No. 319/2013, evaluation fees regulated under Ordinance of the Government of the Slovak Republic No 340/2013
Evaluation of active substances	<ul style="list-style-type: none"> Administrative fee= 2.000€ for 1 PT (per additional PT not specified) Evaluation fee= 170.000€ for 1 PT, 50.000€ per additional PT Total fee for 1 PT =172.000€
Authorisation of BPs	<ul style="list-style-type: none"> Administrative fee= 750€ for 1 BP, 1.250€ for 1 BP family Evaluation fee= 70.000€ for 1 BP, 10.000€ for any other BP Total fee for 1 BP=70.750€
Mutual recognition of authorisations	<p>Fee for mutual recognition in sequence:</p> <ul style="list-style-type: none"> Administrative fee= 500€ for 1 BP, 750€ for 1 BP family Evaluation fee= 6.000€ for 1 BP, 8.000€ for 1 BP family Total fee for mutual recognition in sequence for 1 BP=6.500€, for 1 BP family: 8.750€ <p>Fee for mutual recognition in parallel:</p> <ul style="list-style-type: none"> Administrative fee= 500€ for 1 BP, 750€ for 1 BP family Evaluation fee for 1 BP in parallel: 7000€, evaluation for 1 BP family in parallel: 9000€ Total fee for mutual recognition in parallel for 1 BP: 7500€, for 1 BP family: 9750€
Annual fee	<ul style="list-style-type: none"> Inclusion of a BP in the register for BPs made available on Slovakia's market=300€ Annual fee for a BP placed on the market based on application for national authorisation or based on application for Union authorisation for which the centre was the evaluating authority: 350€ for 1 BP, 750€ for 1 BP family Annual fee for a BP placed on the market based on application for mutual recognition in sequence or in parallel: 300 for 1 BP, 400€ for 1 BP family Annual fee for a BP placed on the market based on application for parallel trade in accordance with a specific regulation: 200€ Annual fee for a BP placed on the market based on a specific regulation: 150€
Measures in favour of SMEs	No
Comments	Option C of the guidance document. Top-up and additional fees apply.

SLOVENIA	
Link to legislation	http://www.uk.gov.si/si/zakonodaja_in_dokumenti/veljavni_predpisi/biocidni_proizvodi/
Evaluation of active substances	117.000 € for 1 PT, 58.400€ per additional PT
Authorisation of BPs	13.500 € for 1 BP, 25.800€ for 1 BP family
Mutual recognition of authorisations	2.500 € for 1 BP, 3.700€ for 1 BP family
Annual fee	No.
Measures in favour of SMEs	No.
Comments	Option C of the guidance document. Top-up and additional fees.

SPAIN	
Link to legislation	http://www.msssi.gob.es/en/ciudadanos/saludAmbLaboral/prodQuimicos/sustPreparatorias/biocidas/NuevoReglamento.htm
Evaluation of active substances	116.040€ for 1 PT, no fee established for additional PTs
Authorisation of BPs	2.436,9€ for 1 BP, 2.436,9€ for 1 BP family
Mutual recognition of authorisations	1.160,4€ for 1 BP, 1.160,4€ for 1 BP family
Annual fee	No
Measures in favour of SMEs	No
Comments	Option C of the guidance document? Top-up and additional fees? Law in process of adoption.

SWEDEN

Link to legislation	<p>Overview of fees for BPs: http://www.kemi.se/Documents/Bekampningsmedel/Avgifter/Application-Fees-BP.pdf</p> <p>Overview of fees for AS: http://www.kemi.se/Documents/Bekampningsmedel/Avgifter/Prislista_verksamma_biocid_EN.pdf</p> <p>Tool for calculation of application fee: http://webapps.kemi.se/bkmavgifter/BeraknaAnsokningsavgift.aspx</p>
Evaluation of active substances	<ul style="list-style-type: none"> Basic fee for 1 PT (application for approval by one company only): 3.800.000 SEK=413632.5€¹⁰+ additional fees might apply according to nature and scope of procedure Basic fee for separate application for an additional PT: 3.800.000 SEK=413632.5€+ additional fees might apply according to nature and scope of procedure
Authorisation of BPs	<ul style="list-style-type: none"> Basic fee= 300.000 SEK=32619.7€ for 1 BP Basic fee= 600.000 SEK=65239.4€ for 1 BP family+ additional fees apply according to nature and scope of procedure (categories of extra fees from A to G)
Mutual recognition of authorisations	120.000 SEK=13047.9€ for 1 BP, 240.000 SEK=26095.8€ for 1 BP family+ additional fees
Annual fee	The annual fee is based on the amount of BPs sold the year before, e.g 2013 as reference year for 2014 (4% of the sales). Minimum fee=2.000 SEK=217.7€, maximum fee=350.000 SEK=38097.7€.
Measures in favour of SMEs	Provisions include a possibility of splitting payments into several instalments and phases, according to Chapter 9 Section 1 in the Ordinance (2013:63) on Fees for Pesticides (currently only available in Swedish). http://www.kemi.se/en/Content/Pesticides/Charges/
Comments	Option C of the guidance document. Top-up and additional fees according to complexity of evaluation.

UNITED KINGDOM	
Link to legislation	http://www.legislation.gov.uk/uksi/2013/1507/contents/made
Evaluation of active substances	£447 per day (adjusted pro rata for parts of a day)- average for active substance evaluation=£182.990= 234032.5€ ¹¹
Authorisation of BPs	£393 per day- average for biocidal product authorisation=£9.770= 12495.2€
Mutual recognition of authorisations	£393 per day- average for mutual recognition=£3.920= 5013.4€
Annual fee	A "General Industry Charge" (GIC), which is charged under the Biocidal Products (Fees and Charges) Regulations 2013, applies industry-wide annually to cover the costs for ongoing general activity carried out by UK CAs in operating the biocides regulatory framework – e.g: for 2012/2013, GIC= 596£ and the amount recovered=370.000£
Measures in favour of SMEs	No
Comments	Option D of the guidance document. An initial fee is charged based upon an estimate of the level of input required. On completion of the AS or PT evaluation, if more resource input was required beyond the initial estimate then an additional top up fee will be requested. Conversely, should the whole of the initial fee not be required then a refund is made.

ICELAND	
Link to legislation	Hyperlink?
Evaluation of active substances	Service not provided.
Authorisation of BPs	2.159.000 ISK=14076,7€ ¹² for 1 PT, extra charge of 541.000 ISK=3527,3€ for additional AS
Mutual recognition of authorisations	541.000 ISK=3527,9€ for 1 BP/for 1 BP family?
Annual fee	No
Measures in favour of SMEs	No specific measures (small market/companies).
Comments	Option B of the guidance document. Refunds planned for up to 75% of initial fees. Final costs are higher than presented fees as service is outsourced. Top-up and additional fees?

NORWAY	
Link to legislation	http://lovdata.no/dokument/SF/forskrift/2014-04-10-548
Evaluation of active substances	2.260.000 NOK=269368.3€ ¹³ for 1 PT, 1.130.000 NOK=134684.2€ per additional PT
Authorisation of BPs	452.000 NOK=53873.7€ for 1 BP, 904.000 NOK=107747.3€ for 1 BP family
Mutual recognition of authorisations	56.500 NOK=6734.2€ for 1 BP, 113.000 NOK=13468.4€ for 1 BP family
Annual fee	<p>Basic fee= 1.500 NOK=178.8€ per authorised BP, 3.000 NOK=357.6€ per authorised BP family</p> <p>A basic annual fee applies to registered BP and BP families. Additionally, a variable annual fee applies based on the sales volume (reported to the National Product Register for the preceding year) and the hazardous properties of the BP (i.e. the classification and labeling of the BP). The details on the purpose of the annual fee are stated in paragraph 4 of the Norwegian biocide regulation (implementing the BPR). The annual fee should cover the actual expenses of the services provided by the authorities (all expenses, including enforcement, which are not directly connected to the handling of application for product authorisation).</p>
Measures in favour of SMEs	No specific measures.
Comments	Option C of the guidance document. Top-up and additional fees.

13 1 EUR = 8.39792 NOK (20/10/2014)

SWITZERLAND	
Link to legislation	http://www.admin.ch/opc/fr/classified-compilation/20021524/index.html
Evaluation of active substances	For 1 PT: <ul style="list-style-type: none">• Minimum fee= 15.000 CHF= 12437.8€¹⁴• Maximum fee=60.000 CHF=49751.2€
Authorisation of BPs	For 1 BP: <ul style="list-style-type: none">• Minimum fee= 15.000 CHF=12437.8€• Maximum fee=60.000 CHF=49751.2€ For 1 BP family: <ul style="list-style-type: none">• Minimum fee= 27.000 CHF=22388.1€• Maximum fee=108.000 CHF=89552.3€
Mutual recognition of authorisations	For 1 BP: <ul style="list-style-type: none">• B Minimum fee= 5.000 CHF=4145.9€• Maximum fee=10.000 CHF=8291.9€ For 1 BP family: <ul style="list-style-type: none">• Minimum fee= 9.000 CHF=7462.7€• Maximum fee=18.000 CHF=14925.4€
Annual fee	No
Measures in favour of SMEs	No, but currently under evaluation.
Comments	Option A of the guidance document. Top-up and additional fees.

14 1 EUR = 1.20620 CHF (27/10/2014)