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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the implementation of the Union authorisation of biocidal products in accordance with Article 42(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products

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1. INTRODUCTION

Regulation (EU) 528/2012[1], which is applicable since 1 September 2013, lays down the rules for the placing on the market and use of biocidal products. This Regulation aims at improving the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment[2]. It repealed Directive 98/8/EC of the European Parliament and of the Council[3].

Regulation (EU) 528/2012 establishes a two-step approach in order to achieve the above-mentioned goals. Active substances must be included in Annex I to that Regulation (the so-called "low-risk active substances") or approved at the Union level and included in a Union list of approved active substances before they can be used in biocidal products[4]. Then biocidal products containing any active substance require an authorisation, as described further down, before they can be placed on the market and used.

Regulation (EU) 528/2012 introduced the concept of a biocidal product family, as defined in Article 3(1)(s) of the Regulation. Accordingly, one product authorisation may cover a group of similar biocidal products. This concept also allows the holder of the authorisation to place on the market new products falling within the boundaries of the family following a simple notification process in accordance with Article 17(6) of the Regulation.

Article 17(7) of Regulation (EU) 528/2012 also introduced the possibility to authorise biocidal products for the same or different enterprises under the same terms and conditions. Details of this so-called “same biocidal product” procedure are laid down by Commission Implementing Regulation (EU) No 414/2013[5]. Applications under this Regulation are linked to a related reference product, which can be an already authorised product or a product being subject to an application in the context of the different authorisation procedures established in Regulation (EU) 528/2012, which are described in the paragraph below.

Regulation (EU) 528/2012 lays down different application routes for the authorisation of biocidal products[6]. Depending on the properties of the active substance used in the biocidal product and the targeted markets in the Union, applicants may choose the most appropriate route:

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[1] Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1.).

[2] Additional information on Regulation (EU) No 528/2012 is available at https://ec.europa.eu/health/biocides/regulation_en and https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr

[3] Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1.).

[4] Additional information on the approval of active substances for use in biocidal products is available at https://ec.europa.eu/health/biocides/active_substances_en and https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances

[5] Commission Implementing Regulation (EU) No 414/2013 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 (OJ L 125, 7.5.2013, p. 4.).

[6] Additional information on the authorisation of biocidal products is available at https://ec.europa.eu/health/biocides/biocidal_products_en and https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products

- a simplified authorisation procedure referred to in Chapter V (Articles 25 to 28) of the Regulation, which provides for an accelerated authorisation of products containing only low risk active substances included in Annex I to the Regulation.
- a national authorisation procedure referred to in Chapter VI (Articles 29 to 31) of the Regulation, which provides for the authorisation in a Member State of biocidal products containing any active substance (either in the Union list or in Annex I to the Regulation);
- mutual recognition of national authorisations referred to in Chapter VII (Articles 33 to 39) of the Regulation in several Member States either at the same time or sequentially.
- a Union authorisation[7] referred to in Chapter VIII (Articles 41 to 46) of the Regulation, which is valid in all Member States.

The possibility for a Union authorisation did not exist in Directive 98/8/EC, the predecessor of Regulation (EU) No 528/2012. As defined in Article 3(1)(n) of the Regulation, a Union authorisation is granted by the Commission and aims at facilitating the making available on the market throughout the Union of certain biocidal products with similar conditions of use in all Member States. Whether a biocidal product has similar conditions of use across the Union may be assessed by Member States, ECHA and the Commission already before the formal submission of the application (i.e. the so-called "pre-submission phase") in accordance with agreed Union guidance[8]. Article 42(1) of Regulation (EU) 528/2012 specifies that the Union authorisation procedure is not possible for biocidal products that contain active substances that fall under Article 5 of the Regulation (i.e. meeting the exclusion criteria) and those of product-types 14, 15, 17, 20 and 21.

While the cost of preparing the file and the time for issuing a Union authorisation is approximately similar to the alternative application process of mutual recognition in parallel, it gives the authorisation holder direct access to the markets of all EU Member States.

In a nutshell, the procedure for Union authorisation is the following: the European Chemicals Agency (ECHA) receives the application and, following its assessment by an evaluating competent authority of a Member State, ECHA organises a peer review process resulting in an opinion delivered by its Biocidal Products Committee (BPC). This opinion will be the basis for the Commission to decide on whether or not to grant the Union authorisation, and under which conditions. ECHA charges fees for the services provided in the context of Union authorisation procedures. These fees are laid down in Commission Implementing Regulation (EU) No 564/2013[9].

Article 42 (3) of Regulation (EU) No 528/2012 introduced an obligation for the Commission to report to the European Parliament and the Council on Union authorisation of biocidal products by 31 December 2017:

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[7] Additional information on Union authorisation is available at https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products/union-authorisation

[8] CA-Feb13-Doc.5.1.e – Final on the definition of similar conditions of use across the Union, available at https://circabc.europa.eu/w/browse/c39eb3a0-628a-4626-97ca-a86cfe492917

[9] Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 19.6.2013, p. 17).

"3. The Commission shall submit a report to the European Parliament and the Council on the application of this Article by 31 December 2017. That report shall contain an assessment of the exclusion of product-types 14, 15, 17, 20 and 21 from the Union authorisation.

The report shall, if appropriate, be accompanied by relevant proposals for adoption in accordance with the ordinary legislative procedure".

By 31 December 2017, no Union authorisation has been granted yet, as the regulatory process for the first applications requesting a Union authorisation has not been completed. Therefore, the Commission is not in a position to make a comprehensive analysis of the functioning of current provisions in the Regulation on Union authorisation, including the exclusion of the above-mentioned product-types 14, 15, 17, 20 and 21 from the Union authorisation. Gaining further experience is needed before any firm conclusions can be drawn and any relevant proposals for changes can be considered.

Consequently, this report provides a factual overview of the applications for Union authorisation submitted until 1 October 2017 and some preliminary conclusions based on the limited experience gained so far with the existing applications for Union authorisation.

2. NUMBER AND TYPE OF APPLICATIONS FOR UNION AUTHORISATION

Table 1 shows the number of Union authorisation applications submitted over the last three years. It reflects whether these applications have been submitted in accordance with Article 43 of Regulation (EU) No 528/2012 or under Article 4 of Commission Implementing Regulation (EU) No 414/2013 as "same biocidal products", as well as the type of authorisation sought (single biocidal product or biocidal product family as defined in Article 3(1)(r) and (s) of Regulation (EU) No 528/2012, respectively).

Table 1: Number of applications for Union authorisation submitted split by type of procedure, year of submission and type of authorisation sought.

	Year of submission						
	2015		2016		2017		
	Type of authorisation sought		**Type of authorisation sought**		**Type of authorisation sought**		
Type of procedure	Single biocidal product	Biocidal product family	Single biocidal product	Biocidal product family	Single biocidal product	Biocidal product family	Total by type of procedure
Article 43 of Regulation (EU) No 528/2012	0	12	5	12	5	36	70
Article 4 of Commission Implementing Regulation (EU)	0	2	1	8	9	25	45

No 414/2013							
Subtotal by type of authorisation/year	0	14	6	20	14	61	**TOTAL**
Total by year	14		26		75		**115**

The first application for Union authorisation was submitted in September 2015. Until the end of 2017, a total of 115 applications for Union authorisations have been submitted, 70 (60.9%) thereof under Article 43 of Regulation (EU) No 528/2012 while 45 (39.1%) have been submitted under Article 4 of Commission Implementing Regulation (EU) No 414/2013. Regarding the type of authorisation sought, 20 applications (17.4%) involved single biocidal products while 95 (82.6%) involved biocidal product families. This latter figure is significantly higher than the estimates in a survey carried out by two industry associations[10] in 2015, which estimated that 44% of the total applications planned to be submitted in the next few years would be for biocidal product families.

The figures in Table 1 show an increasing trend in the number of applications submitted over time. The deadline for the submission of applications for product authorisation, which in accordance with Article 89(3) of Regulation (EU) No 528/2012 corresponds to the date of approval of the relevant active substance(s) contained in the biocidal product, seems to be the main driving factor for this trend. For instance, the number of applications submitted in 2017 reflects the deadlines for certain widely used disinfectants (e.g. hydrogen peroxide or peracetic acid). The above-mentioned increasing trend can also be seen as an indication that Union authorisation has become more attractive to companies operating in the biocides sector, especially for the authorisation of biocidal product families. Therefore, it is interesting to compare the number of applications received with some estimations made in the past.

Tables 2 and 3 show the number of applications submitted compared with the estimates considered in the background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision[11].

Table 2: Number of applications for Union authorisation submitted in 2016 and 2017 compared to the estimates for three scenarios (pessimistic, baseline and optimistic).

	2016	**2017**	**Total**
Pessimistic scenario	*16*	*27*	*43*
Baseline scenario	*20*	*35*	*55*
Optimistic scenario	*23*	*54*	*77*
Applications submitted under Article 43 of Regulation (EU) No 528/2012 only	17	41	58
Total number of applications submitted, including applications under Article 4 of Commission Implementing Regulation (EU) No 414/2013	26	75	101

[10] A.I.S.E. & EBPF survey on the BPR Impact on Biocidal Products and Innovation - 2015, available at https://www.aise.eu/documents/document/20160212173604-aise_ebpf_survey_bpr_2015_-_report.pdf

[11] Ecorys, 15 April 2016. Available at: https://echa.europa.eu/documents/10162/2200151/mb_25_2016_bpr_fee_model_en.pdf/2eaaeec2-4b6e-448f-91ad-d9181b11b938

Table 3: Number of applications for Union authorisation submitted in 2016 and 2017 considering the type of authorisation sought compared to the estimates for the three scenarios.

Applications for single biocidal products	**2016**	**2017**	**Total**
Pessimistic scenario	*6*	*13*	*29*
Baseline scenario	*10*	*16*	*26*
Optimistic scenario	*11*	*27*	*38*
Applications submitted under Article 43 of Regulation (EU) No 528/2012 only	5	5	10
Total number of applications submitted, including applications under Article 4 of Commission Implementing Regulation (EU) No 414/2013	6	9	15
Applications for biocidal product families	**2016**	**2017**	**Total**
Pessimistic scenario	*10*	*14*	*24*
Baseline scenario	*10*	*19*	*29*
Optimistic scenario	*12*	*27*	*39*
Applications submitted under Article 43 of Regulation (EU) No 528/2012 only	12	36	48
Total number of applications submitted, including applications under Article 4 of Commission Implementing Regulation (EU) No 414/2013	20	61	81

The figures in Table 2 show that the number of applications submitted under Article 43 of Regulation (EU) No 528/2012 is similar to the estimates for the baseline scenario in the study. However, the total number of applications (i.e. including the applications under Article 4 of Commission Implementing Regulation (EU) No 414/2013) is clearly above the estimates in the optimistic scenario.

The figures in Table 3 also indicate that the number of applications submitted for single biocidal products, even when considering the total number of applications (i.e. including applications under Article 4 of Commission Implementing Regulation (EU) No 414/2013), is clearly below the estimates in the pessimistic scenario. The contrary applies to the number of applications submitted under Article 43 of Regulation (EU) No 528/2012 for biocidal product families, which is clearly above the estimates in the optimistic scenario. This evidence is even more significant when considering the total number of applications (i.e. including applications under Article 4 of Commission Implementing Regulation (EU) No 414/2013), as the number of applications are double those of the estimates in the optimistic scenario.

Overall, the available data show that the Union authorisation procedure is mainly used by applicants to request the authorisation of biocidal product families that cover a high number of existing (and/or new) products in the markets of Member States. This finding is also consistent with the survey carried out by the two industry associations in 2015, which indicated that about 75% of products expected to remain on the market in the future (from that survey) were intended to be grouped into biocidal product families.

The Union authorisation of a biocidal product family thus seems to be attractive in terms of expected cost savings and reduced administrative burden for applicants under the current fee rates laid down in Commission Implementing Regulation (EU) No 564/2013.

Another possible driver to apply for authorisation of biocidal products families may be the amendment of Commission Implementing Regulation (EU) No 414/2013 made in 2016[12]. This amendment introduced the possibility to go from wider to narrower authorisations (i.e. from a biocidal product family to a subset of one or more of the individual products included in the family) or markets (i.e. from Union authorisation to national authorisation). This means in practice that companies operating in one Member State may support their existing products through applications for national authorisation of a same biocidal product of a biocidal product belonging to an application for Union authorisation of a biocidal product family. So far, 14 of the applications for Union authorisation submitted in 2017 are acting as reference product for 135 applications submitted to competent authorities of Member States in accordance with Article 3(1a) of Commission Implementing Regulation (EU) No 414/2013.

3. ACTIVE SUBSTANCES AND PRODUCT-TYPES FOR WHICH UNION AUTHORISATION APPLICATIONS HAVE BEEN SUBMITTED

Table 4 shows the active substances and the relevant product types for which applications for Union authorisation have been submitted.

Table 4: Number of applications for Union authorisation split by active substance(s) and product-type(s) as defined in Annex V to Regulation (EU) No 528/2012.

Active substance(s)	Product-type(s)	Total
Iodine	3	6
Iodine (as PVP-iodine)	3	1
Iodine & PVP-iodine	3, 4	4
Octanoic acid & decanoic acid	4	1
Octanoic acid	4	1
Propan-2-ol	1, 2, 4	16
Hydrogen Peroxide	1, 2, 3, 4, 5	25
Glutaraldehyde[13] & CMIT/MIT	2, 4	2
Glutaraldehyde[13]	2, 4, 6, 11, 12	5
CMIT/MIT	2, 4, 6, 11, 12, 13	17
Peracetic acid	2, 3, 4, 5, 11, 12	30
Biphenyl-2-ol	6, 13	1
Clothianidin[13] & pyriproxyfen	18	2
Transfluthrin	18	1
Permethrin	18	2
Permethrin & S-methoprene	18	1
Total	**-**	**115**

[12] Commission Implementing Regulation (EU) 2016/1802 of 11 October 2016 amending Implementing Regulation (EU) No 414/2013 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 (OJ L 275, 12.10.2016, p. 34.).

[13] Active substances meeting the substitution criteria as per Article 10(1) of Regulation (EU) No 528/2012. For these applications, a comparative assessment pursuant to Article 23 of that Regulation must be performed.

Table 5 shows the distribution of applications for Union authorisation according to the main groups of product-types that are eligible for the Union authorisation procedure.

Table 5: Number of applications for Union authorisation split by the main groups of product-type(s) as defined in Annex V to Regulation (EU) No 528/2012.

Main Group	**Number of applications (%)**
Disinfectants (product-types 1 to 5)	56 (48.7)
Preservatives (product-types 6 to 13)	1 (0.8)
Disinfectants and preservatives	52 (45.2)
Pest control (product-types 18 and 19)	6 (5.2)
Total (%)	115 (100)

The product-types involved in the current applications are consistent with the provisions in Article 42(1) of Regulation (EU) No 528/2012, which establish the progressive authorisation of different product-types under Union authorisation. The main group 'disinfectants' represents almost half of the applications (48.7%)[14], followed by applications including a combination of uses as disinfectants and preservatives (45.2%) and finally by insecticides (5.2%) which corresponds to product-type 18. No application for Union authorisation for repellents or attractants (product-type 19) has been submitted so far.

Most applications for Union authorisation (98 of the total 115, i.e. 85%) are intended for more than one product-type. This is in particular relevant in case of applications for authorisation of biocidal product families, where it must be decided whether some of the intended uses in the application can be considered to be "similar" as required by the definition of a biocidal product family in Article 3(1)(s) of Regulation (EU) No 528/2012.

Applications for Union authorisation concern 16 active substances representing 38 active substance/product-type combinations. All of these are existing active substances as defined in Article 3(1)(d) of Regulation (EU) No 528/2012. None of the applications involves a new active substance as defined in Article 3(1)(e) of Regulation (EU) No 528/2012, while the Union list of approved active substances which may be used in biocidal products already includes 8 new active substances that are eligible for the Union authorisation procedure (i.e. new active substances not meeting the exclusion criteria referred to in Article 5(1) of the Regulation).

These 38 active substance/product-type combinations included in the applications for Union authorisation represent 42.7% of the 89 combinations that were eligible for Union authorisation and for which the deadline for application for product authorisation according to Article 89(3) of the Regulation fell between 1 September 2013 and 1 October 2017. The 16 active substances represent 31% of the 52 approved active substances that were eligible for Union authorisation during that period of time.

[14] It has to be noted that disinfectants represent the largest group of product-types, as reflected in the Industry survey of 2015.

Finally, only 2 out of the 16 active substances fulfil one of the substitution criteria referred to in Article 10(1)(b) to (f) of Regulation (EU) No 528/2012. This finding is consistent with the objective of discouraging prospective applicants to submit applications for Union authorisation of products containing active substances fulfilling the substitution criteria, as indicated in Recital (4) of Commission Implementing Regulation (EU) No 564/2013. The additional fee of 40,000 Euros when the evaluating competent authority has to perform a comparative assessment in accordance with Article 23 of the Regulation, the validity of the Union authorisation being limited to 5 years only and the lack of any fee reduction for SMEs seem to have contributed to achieve the above-mentioned policy objective.

4. MEMBER STATES THAT ARE EVALUATING THE APPLICATIONS FOR UNION AUTHORISATION

Table 6 provides information on the Member States acting as the evaluating competent authority referred to in Articles 43 and 44 of Regulation (EU) No 528/2012. It has to be noted that pursuant to Article 4(6) of Commission Implementing Regulation (EU) No 414/2013, for the 45 applications submitted under this procedure, the role of the evaluating competent authority is attributed to ECHA. This role is mainly restricted to the validation of the application, as there is no technical assessment of the same biocidal product (i.e. it relies on the assessment of the related reference product which is first conducted by an evaluating Member State).

Table 6: Distribution of the 70 applications for Union authorisation submitted under Article 43 of Regulation (EU) No 528/2012 with regard to the Member State acting as evaluating competent authority.

Member State	Total	*Evaluation fee for a biocidal product family (Euros)*[15]
Austria	4	*90.000,00*
Belgium	3	*30.000,00*
Germany	7	*90.000,00*
Denmark	2	*54.690,00*
Finland	1	*Basic fee of 54.000,00 with a maximum fee of 152.000,00 depending on the complexity of the application*
France	3	*80.000,00*
Latvia	1	*77.048,20*
The Netherlands	41	*Basic fee of 40.000,00 with a gradual fee depending on the complexity of the application*
United Kingdom	8	*By hours spent on the application*
Total	70	

[15] These figures are based on the information available in Annex 3 to the Ecorys report and some update provided by the involved Member States. In Belgium and the Netherlands new fees apply as from 1 January 2018 (BE: 50.000 Euros + 500 Euros per product; NL: 45.000 Euros + gradual fee depending on the complexity of the application).

The information in Table 6 shows that the evaluation of applications is not distributed among the Member States in a balanced way. 41 out of the 70 applications (58%) are assessed by one Member State (the Netherlands).

In fact, Article 43(1) of Regulation (EU) No 528/2012 gives the applicant the right to freely choose the competent authority of the Member State that will evaluate the application, provided that there is written confirmation that that competent authority agrees to do so. There might be different driving factors motivating the applicants' choice of Member States. Among those factors, the amount of the fees charged for the evaluation of the application seems to play an important role. However, other non-quantifiable elements such as the willingness of Member States to act as evaluating competent authority (which must be confirmed in writing before submission of the application) might also be relevant.

It should be noted that different applicants submitted similar applications for the same active/product-type combinations to different evaluating competent authorities. This led to a need for an intensive coordination activity by ECHA in order to harmonise the evaluations, where relevant, as much as possible. This fact points out the key role to be played by ECHA in terms of coordinating activities during the evaluating phase, even before the peer review process.

5. STATUS OF THE APPLICATIONS FOR UNION AUTHORISATION

All the applications submitted so far under Article 43 of the Regulation have been considered as concerning biocidal products having similar conditions of use across the Union. In the context of the "pre-submission phase" during which this verification is made, , it is also checked whether the product falls within the scope of the Regulation and if it is allocated to the appropriate product-type(s). A scope issue was raised affecting 5 applications for the same active substance/product type combination. Following a formal request from Germany, the Commission took a decision pursuant to Article 3(3)[16] of Regulation (EU) No 528/2012 and concluded that the products did fall under the scope of the Regulation.

Table 7 provides an overview of state of progress of the applications for Union authorisation submitted according to the different procedural steps referred to in Articles 43 and 44 of Regulation (EU) No 528/2012. These procedural steps are:

- the acceptance of the application by ECHA;
- the validation and the evaluation of the application by the evaluating competent authority;
- the peer review by ECHA leading to the preparation of the ECHA opinion; and
- the final decision on whether the Union authorisation can be granted by the Commission through implementing acts adopted in accordance with the examination procedure.

[16] Commission Implementing Decision (EU) 2016/904 of 8 June 2016 pursuant to Article 3(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council on propan-2-ol containing products used for hand disinfection (OJ L 152, 9.6.2016, p. 45.).

Regarding the applications submitted under Commission Implementing Regulation (EU) No 414/2013, table 7 refers to:

- the acceptance and the validation by ECHA;
- the preparation of the ECHA opinion; and
- the final decision on whether the Union authorisation can be granted by the Commission through implementing acts adopted in accordance with the examination procedure.

Table 7: State of progress of the applications submitted for Union authorisation according to the different procedural steps referred to in Articles 43 and 44 of Regulation (EU) No 528/2012 or in Articles 4 and 6 of Commission Implementing Regulation (EU) No 414/2013.

	Procedural step					
Type of procedure	**Acceptance**	**Validation**	**Evaluation**	**Peer review - ECHA level**	**Commission Decision**	**Total**
Article 43 of Regulation (EU) No 528/2012	11	19	37	3	0	70
Article 4 of Commission Implementing Regulation (EU) No 414/2013	10	15	20*	0	0	45
Total	21	34	57	3	0	**115**

*Applications already validated by ECHA and for which the related reference products is under evaluation.

The evaluation phase has only been completed for 3 applications so far, and such limited sample does not allow any robust analysis of the available data. However, as 40 and 20 applications have been already validated by the evaluating competent authorities or by ECHA, respectively, the functioning of these processes can be further analysed.

Table 8 provides information on the minimum, maximum and median time taken for the whole validation period (in days). Therefore, this period includes any suspension of the validation in order to request further information to applicants in accordance with Article 43(4) of Regulation (EU) No 528/2012 or Article 4(4) of Commission Implementing Regulation (EU) No 414/2013).

Table 8: Minimum, maximum and median of time (days) taken for the validation step.

Type of procedure	**Number of applications validated**	**Minimum**	**Maximum**	**Median**

Article 43 of Regulation (EU) No 528/2012	40	30 days	541days	198 days
Article 4 of Commission Implementing Regulation (EU) No 414/2013	20	29 days	147 days	73 days

Concerning the amount of time used by the evaluating competent authorities to validate the applications submitted under Article 43 of Regulation (EU) No 528/2012, the median of 198 days shows that half of them have required more than 6 months for the validation. There were a few cases for which the validation of the application took more than one year. This finding indicates that a significant number of applications were incomplete and that the evaluating competent authorities had to suspend the validation in accordance with Article 43(4) of Regulation (EU) No 528/2012. The median for the suspension period was 90 days, with a maximum up to 259 days. This shows that for half of the applications the suspension period was longer than the 90-day period referred to in Article 43(4) of the Regulation, which should not normally be exceeded. Among the possible corrective measures, the following should be further investigated:

- On the applicants' side, better preparing the dossier and checking its completeness before the submission of the application. The combination of applications for the authorisation of biocidal product families involving different product-types might have played a role in the complexity of the dossiers. In this respect, early pre-submission meetings with the evaluating competent authority could be very useful in order to ensure a smooth validation of the application.

- On the evaluating competent authorities' side, avoiding making any assessment of the quality or the adequacy of the data or justifications submitted, as indicated in the second subparagraph of Article 43(3) of Regulation (EU) No 528/2012, should contribute to shortening the time necessary for validation. In the same vein, additional information that is requested during validation should rather be requested during the evaluation.

Article 89(3) provides for a total of 3 years for the authorisation of existing biocidal products under Regulation (EU) No 528/2012. Therefore, a timely validation of the applications is essential in order to keep as much time as possible for the subsequent and more complex procedural steps (assessment by the evaluating competent authority, peer review by ECHA and authorisation by the Commission).

Regarding the amount of time used by ECHA to validate the applications submitted under Article 4 of Commission Implementing Regulation (EU) No 414/2013 for 'same biocidal products', the median of 73 days shows that half of them have required more than 2 months for the validation. This finding indicates that checking the proposed differences between the same product and the related reference product referred to in Article 4(5) of that Regulation may be a complex task, particularly for biocidal product families. It has to be noted though that delays in the validation of these specific applications for 'same biocidal products' do not have significant consequences, as they are put on hold until the assessment of the reference product has been finalised.

6. THE USE OF UNION AUTHORISATION PROCEDURES BY SMALL AND MEDIUM-SIZE ENTERPRISES (SMES)

Table 9 provides information on the share of SMEs among the companies having submitted applications for Union authorisation.

Table 9: Use of Union Authorisation by SMEs.

Indicator	Total	Number of SMEs	% of SMEs
Number of applicants	48	10	20.8
Number of applications under Article 43 of Regulation (EU) No 528/2012 (all)	70	10	14.3
Number of applications under Article 43 of Regulation (EU) No 528/2012 (as single biocidal product)	10	4	40.0
Number of applications under Article 43 of Regulation (EU) No 528/2012 (as biocidal product families)	60	6	10.0
Number of applications under Article 4 of Commission Implementing Regulation (EU) No 414/2013	45	0	0

About 21% of the applicants having submitted Union authorisation applications are SMEs. This is a significantly lower percentage than the estimated overall percentage of SME-companies active in the biocides sector reported in the study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision, according to which the share of SMEs ranges from 73 to 86% according to the size class by turnover or by number of employees, respectively[17].

Union authorisation can be a key instrument for any company to facilitate the making available on the market of biocidal products throughout the Union. It is obvious that large companies have a higher capacity than SMEs to be present in a larger number of Member States. According to the survey carried out in the context of the above-mentioned study, it was estimated that the threshold for choosing Union authorisation was having sales, on average, in more than 10 Member States. Many SMEs, by reason of their size, due to their focus on niche markets or language barriers, may rather be interested in operating in one or few Member States only[18]. This might explain the lower number of SMEs applying for Union authorisation compared to larger companies.

On the other hand, Article 3(1a) of Commission Implementing Regulation (EU) No 414/2013 now allows SMEs to apply for national authorisation of same biocidal products in cases where the related reference product is the subject of an application for Union authorisation. In fact, so far 135 applications have been submitted to competent authorities of Member States referring to 14 applications for Union authorisation. This could be a particularly attractive option for SMEs and might also explain why SMEs have not submitted applications for the same biocidal products at Union level.

[17] See information available at page 78 of the Ecorys report referenced in footnote 10.

[18] This argument was put forward by the relevant accredited stakeholder organisations in the biocides sector (EBPF-Cefic, Aise and EUAPME) and it the main reason triggering the amendment of Commission Implementing Regulation (EU) No 414/2013 in 2016.

Both in the above-mentioned study and industry surveys, companies (in general) indicated the relevance that the annual fee to be paid following the granting of a Union authorisation plays in their choice between Union authorisation or national authorisation followed by mutual recognition. This aspect, together with the lack of a possibility to pay the relevant fees in several instalments, might also have played a role affecting the number of applications for Union authorisation submitted by SMEs.

Although the number of applications under Article 43 of Regulation (EU) No 528/2012 for Union authorisation of single biocidal products is limited (10), the share of applications submitted by SMEs (40%) is higher than the share for the applications for authorisation of biocidal product families (10%). This finding might be due to more reduced product portfolios of SMEs compared to larger companies. However, it could also indicate that some SMEs might still need to increase their capacity, or to make further use of the help of external consultancies, in order to prepare and support more complex dossiers for the authorisation of biocidal product families. It remains to be further analysed how the guidance[19] developed by the Commission in order to support SMEs, and particularly the practical guide on consortia, will have a positive effect in that respect and increase the number applications for Union authorisation submitted by SMEs in the future.

7. PRELIMINARY CONCLUSIONS

The number of applications submitted under Article 43 of Regulation (EU) No 528/2012 is comparable to the baseline estimate in the study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation. However, the total number of applications submitted (i.e. including applications under Article 4 of Commission Implementing Regulation (EU) No 414/2013) is clearly above the estimates in the optimistic scenario in that study. In addition, the trend of submission of applications for Union authorisation over the recent years shows that the procedure is increasingly used.

This finding seems to indicate that Union authorisation is attractive under the current fee rates laid down in Commission Implementing Regulation (EU) No 564/2013, particularly with regard to biocidal product families. However, it will only be possible to fully assess the success of this procedure some years after the actual delivery of Union authorisations. While decision-making on the first four applications is in the final stage, so far no Union authorisation has been granted yet.

The main product-types covered by the current applications are disinfectants (48.7%), followed by applications including a combination of disinfectant and preservative uses (45.2%). Therefore, Union authorisation seems to respond to the needs of applicants to reach the whole Union market for widely used biocidal products with similar conditions of use across EU.

All the 16 actives substances included in the applications are approved existing active substances as defined in Article 3(1)(e) and (d) of Regulation (EU) No 528/2012. Only 2 out of these 16 active substances fulfil one of the substitution criteria referred to in Article 10(1)(b) to (f) of Regulation (EU) No 528/2012. This finding is consistent with the objective

[19] Available at https://echa.europa.eu/practical-guides/bpr-practical-guides

of discouraging applications for Union authorisation of products containing active substances fulfilling the substitution criteria.

The Union authorisation procedure is mainly used by applicants to request the authorisation of biocidal product families (82.6% of the applications) that cover a high number of existing products in the markets of Member States. Taking into account that most applications for Union authorisation are also intended for more than one product-type (85%), this may add a certain degree of difficulty for the evaluating competent authorities to timely validate and assess the applications.

Following the amendment of Commission Implementing Regulation (EU) No 414/2013, applications for Union authorisation are serving as reference products for national applications in accordance with Article 3(1a) of that Regulation (135 so far). This will help applicants, and particularly SMEs, to obtain authorisation for their existing products at Member State level.

The choice of the evaluating competent authority by applicants does not follow a balanced distribution among Member States, and 58% of applications are today assessed by one Member State only. The driving factors behind the applicants' choice of Member States should be further explored in order to find a more balanced distribution of the workload between Member States.

The available information on the validation of the applications by the evaluating competent authorities indicates that a significant proportion of applications was incomplete and required further submission of information. The main reasons leading to this situation and any possible corrective measures have to be further investigated, both on the applicants' and the evaluating competent authorities' sides. In this respect, proper planning of early pre-submission meetings between the applicant and the evaluating competent authority should be further promoted.

About 21% of the applicants having submitted Union authorisation applications are SMEs. The fact that a significant proportion of SMEs may be interested in operating in only a limited number of Member States may play a role in this respect. Some other factors like their capacity to prepare and support dossiers, the role of the amendment to Commission Implementing Regulation (EU) No 414/2013, the level of the reduction of the fees to be payed to ECHA or the possibility to implement a system of payment of fees by instalments should be further considered in order to better understand their effect on the number of applications submitted by SMEs.

The Commission will include a more comprehensive assessment of the Union authorisation procedure in its composite report to the European Parliament and the Council on the implementation of Regulation (EU) No 528/2012 in accordance with Article 65(4) of that Regulation. The composite report will be based on the reports submitted by Members States to the Commission on the implementation of the Regulation in their respective territories, which are due by 30 June 2020 in accordance with Article 65(3) of the Regulation.