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REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

on the implementation 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

{COM(2021) 287 final}

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1. INTRODUCTION

Regulation (EU) No 528/2012[1] (the Biocidal Products Regulation - BPR), which is applicable since 1 September 2013, lays down the rules for the making available on the market and use of biocidal products and articles treated with such products. Biocidal products are used to control unwanted organisms that are harmful to human or animal health or to the environment, or that cause damage to human activities, including pests (e.g. insects, rats or mice) and microorganisms (e.g. bacteria, viruses, mould). Based on Article 114 TFEU, the Regulation aims at improving the functioning of the internal market for biocidal products, while ensuring a high level of protection for human and animal health and the environment[2]. It repealed Directive 98/8/EC of the European Parliament and of the Council[3] (Biocidal Products Directive).

Biocidal products are designed to have impacts on unwanted living organisms. Despite the risks inherent to their use, biocidal products play an important role in the daily life of EU citizens. For example, insecticides and disinfectants are essential for the protection of public health to help control vector-borne diseases (such as malaria, dengue fever, chikungunya, zika), food-borne diseases (such as salmonellosis, listeriosis) or hospital-acquired infections (such as MRSA infection). The crucial role of biocidal products for the protection of public health has been particularly highlighted during the Covid-19 pandemic, where disinfecting products have been critically important in controlling the spread of the disease. Biocidal products are also widely used in materials such as plastics, paints, textiles, wood, etc. to protect these materials against microbial, fungi or insect-induced decay.

The BPR establishes a two-step approach in order to achieve the above-mentioned goals. Active substances, which exercise the action on the target organism(s), must either be approved at the Union level and included in a Union list of approved active substances or be included into Annex I to that Regulation before they can be used in biocidal products[4]. Subsequently, biocidal products containing any active substance require an authorisation, at national or Union level, before they can be made available on the market and used.

The BPR establishes a transitional period in order to implement this system and, by way of exception, biocidal products containing active substances which were already on the market when the BPD came into application and are included in the work programme for the examination of existing biocidal active substances contained in biocidal products (commonly

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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.

known as 'Review Programme') can be made available on the market and used in accordance with national laws of each Member State pending the final decision on the approval of the active substance(s) they contain. Also, pending the decision on the approval of a new active substance, biocidal products containing it may be provisionally authorised for limited periods of time by Member States or the Commission if certain conditions are fulfilled.

Active substances are approved for specified product-types. Annex V to the BPR categorises biocidal products into 22 product-types[5], categorised in four main groups: disinfectants, preservatives, pest control and other biocidal products. The BPR excludes from its scope products that are already regulated by other EU legislations, like plant protection products (within the scope of Regulation (EC) 1107/2009), medicinal products for human use (within the scope of Directive 2001/83/EC and Regulation (EC) 726/2004), veterinary medicinal products (within the scope of Regulation (EU) 2019/6), or preservatives used for food and feedstock (within the scope of Regulation (EC) No 1333/2008 or Regulation (EC) No 1831/2003). Certain products may have a dual use, like detergents being also disinfectant products, and must therefore comply with both legislations (e.g. detergents are regulated under Regulation (EC) 648/2004).

Annex I to the BPR lists active substances that have a more favourable profile as regards impacts to human or animal health or the environment. With a view to encouraging the use of biocidal products containing these active substances, a simplified authorisation procedure is established for such products. Once authorised in a Member State, such products can be made available on the market of other Member States following a simple notification submitted to those other Member States. This list includes for instance certain substances also authorised as food additives, substances exempt from the registration requirements under the REACH Regulation[6], pheromones and other substances considered to have a low toxicity.

The provisions of the BPR developed further certain concepts and procedures, or introduced new ones, compared to its predecessor, the BPD in particular:

- extension of the definition of biocidal product to cover clearly active substances generated *in-situ*;
- the concept of a Biocidal Product Family in order to authorise simultaneously a group of biocidal products with similar uses, same active substance(s), similar composition and similar levels of risk and efficacy;
- the concept of Union authorisation granted by the Commission, which allows the making available on the market of products throughout the Union;
- the concept of mutual recognition in parallel, by means of which a company can request authorisation for a biocidal product in several Member States at the same time.
- specific rules concerning articles treated with biocidal products;

[5] https://echa.europa.eu/regulations/biocidal-products-regulation/product-types.

[6] Such substances are listed in Annex IV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), (OJ L 396 30.12.2006, p. 1).

- the possibility for the Commission, upon request from a Member State, to decide whether a specific product is a biocidal product, a treated article or neither of the two[7].

The European Chemical Agency (ECHA), set up under the REACH Regulation, is responsible for providing technical and scientific support in the implementation of the BPR. Through its Biocidal Products Committee, it provides opinions to the Commission related to approval of active substances, Union authorisation of biocidal products and various other scientific and technical matters. ECHA also produces operational guidance documents and provides advice and assistance to companies via its helpdesk. ECHA is responsible for maintaining the Register for Biocidal Products, which is used by applicants, competent authorities, ECHA and the Commission to (i) submit applications under the BPR, (ii) exchange information during the assessment of the applications and (iii) disseminate information once active substances have been approved and products authorised.

Pursuant to Article 65 of the BPR, Member States and the Commission must report on the implementation of the Regulation. Member States have to submit to the Commission reports on the implementation of the BPR in their territories every five years. Article 65(3) of the BPR, indicates some elements[8] to which particular attention should be given in the reports. Pursuant to Article 65(4) of the BPR, the composite report of the Commission should be drawn up on the basis of the reports provided by Member States and should be submitted to the Council and the European Parliament within 12 months from the deadline for submission of reports by Member States. The deadlines for submission of the first reports from Member States and from the Commission are 30 June 2020 and 30 June 2021, respectively, covering the period from 1 September 2013 (date of entry into application of the BPR) until 31 December 2019.[9] All Member States submitted their reports, with the exception of the Czech Republic[10]. In addition to the information provided by Member States in their reports, this report is also based on data extracted from the dedicated IT platform[11] used by applicants, competent authorities, ECHA and the Commission for the submission and assessment of applications and the exchange of information in relation to procedures under the BPR. The overview report[12] of the fact-finding missions carried out in 2017 and 2018 by the Directorate-General for Health and Food Safety of the European Commission in five Member States in order to monitor and assess the implementation of certain provisions of the BPR was also used as a source of information.

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[7] Since the entry into application of the BPR the Commission received 16 such requests and adopted 9 decisions, published at https://echa.europa.eu/regulations/biocidal-products-regulation/legislation.

[8] (i) information on results of official controls, (ii)information on poisoning and occupational diseases involving biocidal products, (iii) information on adverse environmental effects experienced through using biocidal products and (iv) information on use of nanomaterials in biocidal products and potential risk thereof.

[9] By way of exception, Chapter 10 of this report describes the impact of the Covid-19 pandemic on the implementation of the BPR during 2020.

[10] The reports are available at: https://ec.europa.eu/health/biocides/key_documents_en. [*reports not yet published*]

[11] Register for Biocidal Products, set up according to Article 71 of the BPR.

[12] https://op.europa.eu/en/publication-detail/-/publication/14fbda4b-329f-11ea-ba6e-01aa75ed71a1/language-%20%20%20en/format-PDF/source-112325446

2. COMPETENT AUTHORITIES

Pursuant to Article 81 of the BPR, Member States must designate one or more competent authorities (CAs) responsible for the application of the BPR. Member States must ensure that the CAs have a sufficient number of suitably qualified and experienced staff in order to be able to carry out efficiently and effectively the obligations laid down in the BPR. There are 44 CAs operating in the EU Member States, EEA States and Switzerland[13] (collectively referred to in this document as "Member States"). 20 Member States have designated one single authority responsible for the implementation of the BPR in their territory. In 7 Member States (France, Estonia, Denmark, Germany, Lithuania, Netherlands, Spain) there are two competent authorities, while in 3 Member States (Greece, Portugal, Romania) there are 3 competent authorities. 6 competent authorities operate in Switzerland, which also act as evaluating competent authorities for the applications for active substance approval and biocidal products authorisation accepted by the competent authority of Liechtenstein.

As mentioned in the introduction, in 2017 and 2018 the Directorate-General for Health and Food Safety of the European Commission carried out fact-finding missions in five Member States. The scope of the missions included, among others, the designation of CAs, as well as the communication and co-operation within and between these authorities. The overview report of the fact-finding missions indicates, together with other findings, the main challenges encountered by CAs in their work. One main challenge faced by authorities is insufficient staff resources allocated to perform the tasks required for the implementation of the BPR. Member States highlighted the importance of the work at EU level in order to achieve harmonisation and consistency at Union level in the approval of active substances and authorisation of biocidal products and in general in the implementation of the Regulation. However, due to the lack of resources, not all Member States are able to contribute in the same manner to the work at EU level, with some Member States being more active than the others. The possibility to exchange of experts between competent authorities, as well as the exchange of experiences on how to estimate the upcoming workload in order to allocate resources efficiently, were identified in this report as potentially beneficial to improve the efficiency of the competent authorities.

The Commission expert group called "Competent Authorities for the implementation of Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products" brings together the CAs of all Member States, EEA States and Switzerland in regularly organised meetings (4 to 5 times a year on average). These meetings are also attended by ECHA and observers from stakeholders (industry representatives, NGOs, etc.). It aims at facilitating cooperation between CAs competent authorities, the Commission, and ECHA on the implementation of the BPR in their respective areas of responsibility, and achieving an EU-wide harmonised approach. Some CAs participate actively in this group, while not all are able to attend all meetings.

The Standing Committee on Biocidal Products is made up of representatives of EU countries and is chaired by a representative of the European Commission. It meets regularly (4-5 times a year on average) and delivers opinions on draft implementing measures that the Commission intends to adopt.

[13] The chapter on biocidal product in the agreement between the European Community and the Swiss Confederation on mutual recognition in relation to conformity assessments covers since 14 April 2015 the BPR and the revised Swiss Ordinance on Biocidal Products of 15 July 2014.

2.1. Fees and reductions for small and medium-sized enterprises

All Member States have adopted national legislation setting fees for services that they provide with respect to the procedures under the BPR, in accordance with Article 80(2) of the BPR. The Commission services issued specific guidance to help Member States in the setting of their fee system[14]. In almost all Member States, the fees are expressed as given amounts per specific procedure, except for some, where the fees are calculated based on the actual costs incurred (depending on number of staff involved in a certain procedure and the number of days worked). Iceland has not set fees for active substance-related procedures. Also, in Norway and Hungary fees for procedures related to Union authorisation have not yet been established.

The amount of fees for the various procedures varies greatly between Member States. For example, for an application for approval of an active substance for one product-type, the fees vary between €11,324 in Bulgaria and €421,974 in Sweden. For applications for product authorisation the fees vary between €2,510 in Spain and €100,000 in Cyprus, and for applications for Union authorisation they vary between €4,320 in Bulgaria and €100,000 in Cyprus. The fees for (national or Union) authorisation of biocidal products families are higher than the ones for the authorisation of single biocidal products; in many cases (e.g. Austria, Finland, Poland, Sweden, Greece, Ireland) the amount is double the amount of fees for single products. Table 2.1 illustrates the minimum and maximum amount of fees for the main procedures under the BPR.

Table 2.1: Minimum and maximum fees for BPR procedures and the Member State where they apply

BPR procedure	*Minimum amount**	*Maximum amount**
Active substance approval	€ 11,324 (BG)	€ 421,974 (SE)
Inclusion into Annex I to BPR	€ 10,000 (EL)	€ 332,000 (RO)
Authorisation of a biocidal product (BP)	€ 2,510 (ES)	€ 100,000 (CY)
Authorisation of a biocidal product family (BPF)	€ 6,901 (BG)	€ 200,000 (CY)
Mutual recognition of an authorisation of a BP	€ 400 (LU)	€ 28,256 (LT)
Mutual recognition of an authorisation of a BPF	€ 800 (LU)	€ 30,000 (FR)
Union authorisation of a BP	€ 4,320 (BG)	€ 100,000 (CY)
Union authorisation of a BPF	€ 6,901 (BG)	€ 200,000 (CY)

(* for Member States outside the Eurozone the amounts were converted into euro using the exchange rate of 16 December 2020)

The third subparagraph of Article 80(2) sets up the possibility for Member States to levy annual fees with respect to biocidal products made available on their markets. 18 Member

[14] CA-Dec12-Doc.5.1.b - Final - Note for Guidance on Fees.doc available at: https://circabc.europa.eu/w/browse/b5c900a2-ef66-4a46-996d-00d5a29aee9a

States have chosen to not levy annual fees from product authorisation holders. In Member States where such annual fees are established, they vary between € 67 in Denmark and € 500 in Austria for single biocidal products. These fees are higher for biocidal products families.

Numerous small and medium-sized enterprises (SMEs) are active in the field of biocides. According to the findings of a study conducted for the Commission[15], more than 70% of the companies operating in this field in 2015 were SMEs (see Figure 2.1)

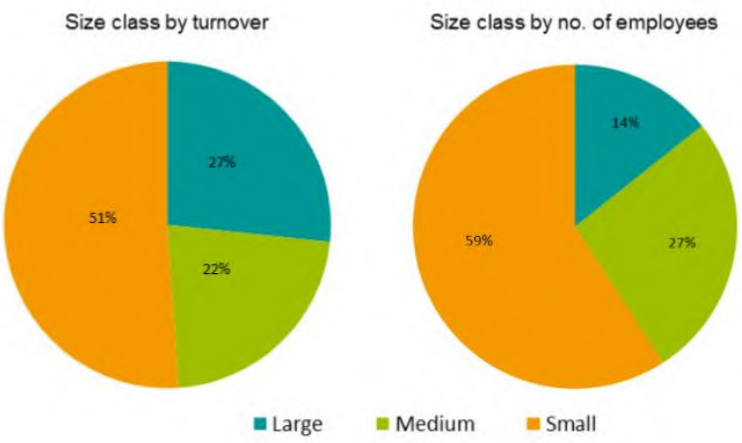

Figure 2.1 Percentage of SMEs in the EU biocides market in 2015

Article 80(3)(c) of the BPR provides that Member States, when setting the fees, should take into account specific needs of SMEs, as appropriate. However, 22 Member States have not adopted specific measures taking into account specific needs of SMEs. In those Member States which adopted measures, these are either reduced fees based on the size (micro, small, medium) of the company (for instance in Belgium, Luxembourg, Ireland, Cyprus) or the possibility of payment of fees in instalments (for example in Austria and Germany).

In addition to fees charged by Member States for the procedures under the BPR, fees must also be paid to ECHA[16] by applicants for (i) active substance related procedures (approval, renewal, inclusion into Annex I to the BPR), (ii) Union authorisation of biocidal products and (iii) other activities (for instance submission of applications for mutual recognitions). Fee reductions for SMEs[17] are foreseen for procedures related to active substance approval and Union authorisation of biocidal products.

[15] Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation and its possible revision, available at: https://echa.europa.eu/documents/10162/2200151/mb_25_2016_bpr_fee_model_en.pdf/2eaaeec2-4b6e-448f-91ad-d9181b11b938

[16] Commission Implementing Regulation (EU) No 564/2013 of 18 June 2013 on the fees and charges payable to the European Chemicals Agency, OJ L 167, 19.6.2013, p. 17–25

[17] The reductions are 60%, 40% and 20% of the standard fee for micro, small and medium enterprises, respectively, for procedures related to active substances and 30%, 20% and 10% of the standard fee for Union authorisation of biocidal products

2.2. Functioning of helpdesks and advice to small and medium enterprises

Article 81(2) requires Member States to provide advice to applicants, in particular to SMEs, and to other interested parties, on their responsibilities and obligations under the BPR. Such advice may be provided by establishing dedicated helpdesks. All Member States have established BPR helpdesks, except for Liechtenstein, which has delegated the relevant tasks to the Swiss helpdesk.

The number of enquiries received by Member States varies significantly. However, three quarters of the helpdesks received on average more than 200 enquiries per year, and half of the helpdesks received on average more than 500 enquiries per year (up to an average of 2000 for Germany). In most of the 25 Member States who provided information[18], the highest number of enquiries was received between 2017 and 2019 - and a slight yearly increase was registered between 2017 and 2019 - while in three Member States the highest number was registered in 2014 (first year after the entry into application of the BPR), notably in Germany, where more than 10,000 enquiries were received that year. Figure 2.2 shows the evolution of the total number of helpdesk enquiries in 25 Member States.

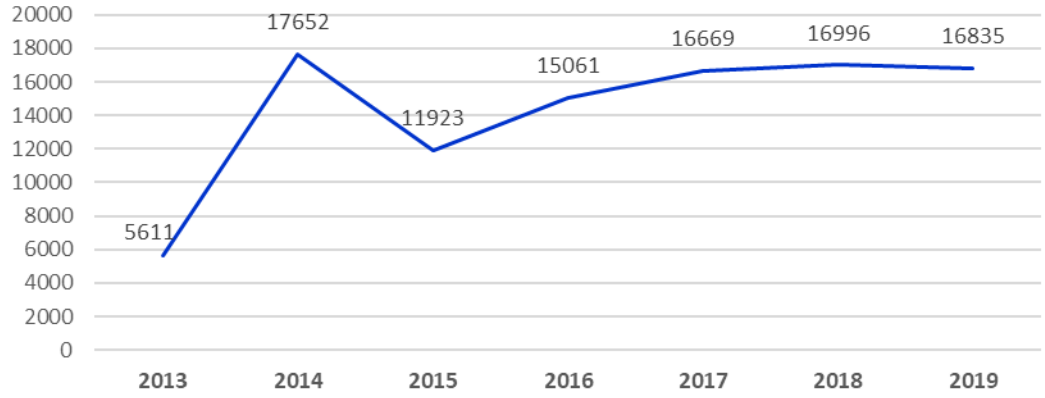

Figure 2.2 Total number of helpdesk enquiries in 25 Member States

Only five Member States were able to provide a breakdown of whether enquiries were related to active substances, biocidal products or treated articles. Where this information is available, it shows that the vast majority of the enquiries (on average more than 90%) was related to biocidal products, while those related to treated articles represented a maximum of 8% of total enquiries, and the remaining ones (around 2%) concerned active substances.

15 Member States indicated that they provide specific advice to SMEs. This is done mainly by means of tailored meetings with SMEs (mostly meetings before the submission of applications for active substance approval or product authorisation), specific conferences and events targeted at SMEs and additional guidance provided to this type of companies.

[18] In six of these Member States data for 2013 and 2014 were not available.

3. ACTIVE SUBSTANCE APPROVAL

Active substances have to be approved at Union level before an authorisation for a biocidal product containing them can be granted. The approval is valid for specified product-type(s).

Applicant must submit its dossier to an evaluating Member State competent authority responsible for its assessment, who forwards its assessment report to ECHA. A peer review by the experts of all other Member States is organised by ECHA within its Biocidal Products Committee (BPC), responsible to prepare, within 270 days an opinion on whether or not the active substance meets the criteria for approval. Based on the ECHA BPC opinion, the European Commission prepares a decision either to approve (with relevant conditions) or not to approve, an active substance, which is subject to an opinion in the Standing Committee of Biocidal Products. The approval of an active substance is limited to period not exceeding 10 years and is renewable. Short approval periods are granted in certain cases, for instance when an active substance meeting the exclusion criteria set out in Article 5(1) of the BPR is approved under one of the derogation possibilities established in Article 5(2).

As set out in Article 6 of the BPR, an application for approval of an active substance must include both a dossier for the active substance and a dossier for at least one representative product containing that active substance, and must demonstrate that the representative biocidal product(s) is (are) safe and effective. The data requirements for the active substance and product dossiers are laid down in Annexes II and III to the BPR, respectively.

3.1. Active substances in the Review Programme

Directive 98/8/EC (the BPD), the predecessor of the BPR, which was the first Union-wide legislation on biocidal products, established a distinction between existing active substances which were on the market in biocidal products on 14 May 2000, and new active substances, which were not on the market in biocidal products on that date. As foreseen in the BPD, a work programme for the examination of the existing active substances, commonly known as the "Review Programme" was set up.

A specific Implementing Regulation[19] laid down the provisions necessary for the implementation of the Review Programme. It listed all existing active substances identified by companies, and among these active substances, those existing substances notified by companies for inclusion in the review programme. In 2003, 954 active substances had been identified[20] as existing active substances. Producers, formulators, associations or Member States expressed their interest to apply for approval of 220 of these active substances, which were included in the Review Programme[21] in 2003, covering a total of 624 active substance/product-type combinations. Rapporteur Member States (Member States performing

[19] Commission Regulation (EC) No 2032/2003 of 4 November 2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market, and amending Regulation (EC) No 1896/2000 (OJ L 307, 24.11.2003, p. 1–96), repealed and replaced in 2007 by Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3–65)

[20] Annex I to Commission Regulation (EC) No 2032/2003 of 4 November 2003.

[21] Annex II to Commission Regulation (EC) No 2032/2003 of 4 November 2003.

the evaluation of the application dossiers) were also designated for each active substance. Most applications for approval of active substances in the Review Programme were submitted between April 2004 and October 2008 according to four successive priority lists, depending on product-types.

After the entry into application of the BPR, the rules for the implementation of the Review Programme were adapted to the provisions of the BPR by Regulation (EU) No 1062/2014[22] (the Review Programme Regulation). The Review Programme Regulation also includes specific procedures for (i) joining or replacing a participant in the Review Programme by mutual agreement, (ii) withdrawing as a participant and (iii) taking over the role of participant in certain situations.

The Review Programme Regulation was amended three times (once in 2017 and twice in 2018), in order to better reflect the actual state of the progress of work programme. In particular, the first revision of 2018[23] was connected to the redefinition of the identity of certain existing active substances generated *in-situ* already covered by the Review Programme. That revision also newly included in the work programme food and feed active substances used for product-type 19 that had benefitted from a previous derogation under Directive 98/8/EC which was no longer valid under the BPR. Around 100 active substance/product-type combinations entries were added to the Review Programme with this revision, which led to an increase of the number of specific evaluations to be performed. The second revision of 2018[24] was needed in order to address the consequences of the withdrawal of the United Kingdom from the European Union: the responsibility for evaluating the applications for 45 active substance-product-type combinations were re-assigned from the United Kingdom to other evaluating Member States.

To ensure a more efficient implementation, the Review Programme Regulation also reorganised the priorities, setting six new priority lists, each with different deadlines for the submission of the assessment reports by the evaluating competent authorities to ECHA and for the submission of the opinions by the Biocidal Products Committee to the Commission. The criteria to group product-types in the priority lists were mainly based on the state of completion of the assessments and the technical relevance, so that assessments conducted for a product-type could be beneficial for the assessment of other related substances. For instance, active substances supported in the Review Programme for product-types 1 to 5 are often the same; active substances for product-types 7, 9 and 10 are often the same and often present similar scientific or borderline issues between one another. The six priority lists and the respective deadlines are indicated in Table 3.1.

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[22] Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014).

[23] Commission Delegated Regulation (EU) 2019/157 of 6 November 2018 amending Annex II to Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 31, 1.2.2019, p. 1–20).

[24] Commission Delegated Regulation (EU) 2019/227 of 28 November 2018 amending Delegated Regulation (EU) No 1062/2014 as regards certain active substances/product-type combinations for which the competent authority of the United Kingdom has been designated as the evaluating competent authority (OJ L 37, 8.2.2019, p. 1–21).

Table 3.1: Priority lists established by the Review Programme Regulation

Priority	Existing active substances for product types	Deadline for submission of the assessment report	Deadline for submission of BPC opinions
1st priority list	8, 14, 16, 18, 19, 21	31/12/2015	31/12/2016
2nd priority list	3, 4, 5	31/12/2016	31/12/2017
3rd priority list	1, 2	31/12/2018	31/12/2019
4th priority list	6, 13	31/12/2019	31/12/2020
5th priority list	7, 9, 10	31/12/2020	31/12/2021
6th priority list	11, 12, 15, 17, 20, 22	31/12/2022	31/06/2024

Although initially foreseen to be completed in 10 years, the duration of the review programme had to be extended – first by amendment to the BPD[25], and subsequently by Regulation (EU) No 736/2013 amending the BPR, which extended the deadline for completion of the review programme to 31 December 2024, based on the estimations available to the Commission at that time and assuming a target of 50 decisions to be adopted per year on average.

On 1 September 2013, the date of entry into application of the BPR, the Commission had adopted 69 decisions[26] on approval or non-approval of existing active substances, covering 73 active substance/product-type combinations, which corresponded to 11% of the Review Programme at that time. The execution of the Review Programme was thus clearly delayed already at that time.

As explained earlier, the first step in the process of the evaluation of the applications for approval of active substances is the submission of the Competent Authority Report (CAR) to ECHA by the evaluating Competent Authority.

The early years of implementation of the BPR were promising in the direction of reaching the target of 50 evaluation per year[27], even if the target was not fully met. However, as shown in Figure 3.1, the number of CARs delivered by the Member States started to drop significantly since 2017, with only one CAR delivered in 2018.

[25] Directive 2009/107/EC of the European Parliament and of the Council of 16 September 2009 amending Directive 98/8/EC concerning the placing of biocidal products on the market as regards the extension of certain time periods (OJ L 262, 6.10.2009, p. 40–42).

[26] One Commission decision to approve or non-approve an active substance may cover one or multiple product-types for the same active substance.

[27] Document CA-Sept13-Doc.8.3-Final-Review Programme of AS, https://circabc.europa.eu/w/browse/8a48f736-853c-4c5f-8fda-92ccc8d30415

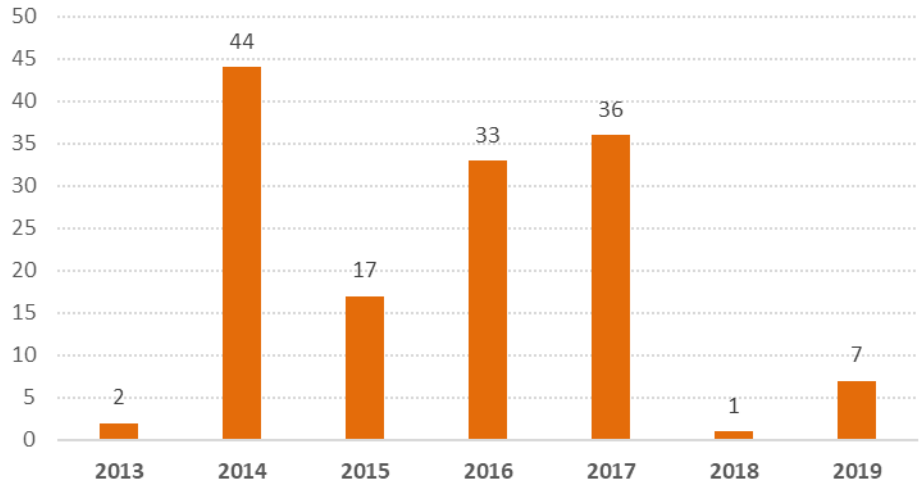


Figure 3.1 Number of Competent Authority Reports submitted per year

Figure 3.2 shows the number of assessment reports submitted between 2013 and 2019 by each Member State.

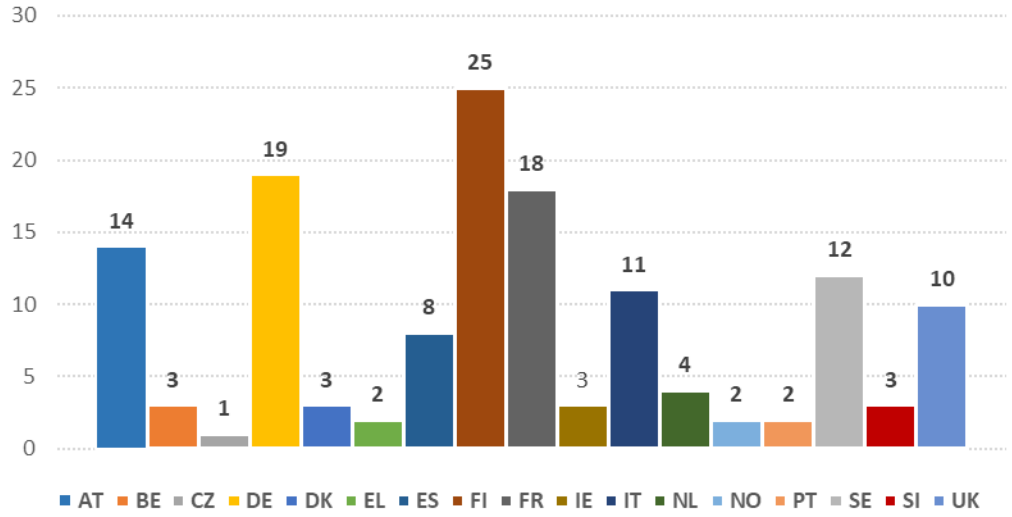


Figure 3.2 Number of Competent Authority Reports submitted, by Rapporteur Member State

When considering all priority lists combined (see Figure 3.3), the best performers are Finland, Ireland, Latvia, Austria, France and Greece (with less than 25% of the active substance/product-type combinations still under evaluation), while the worst performers are Belgium, Hungary, Poland and Portugal, with more than 70% of the active substance/product-type combinations still under evaluation.

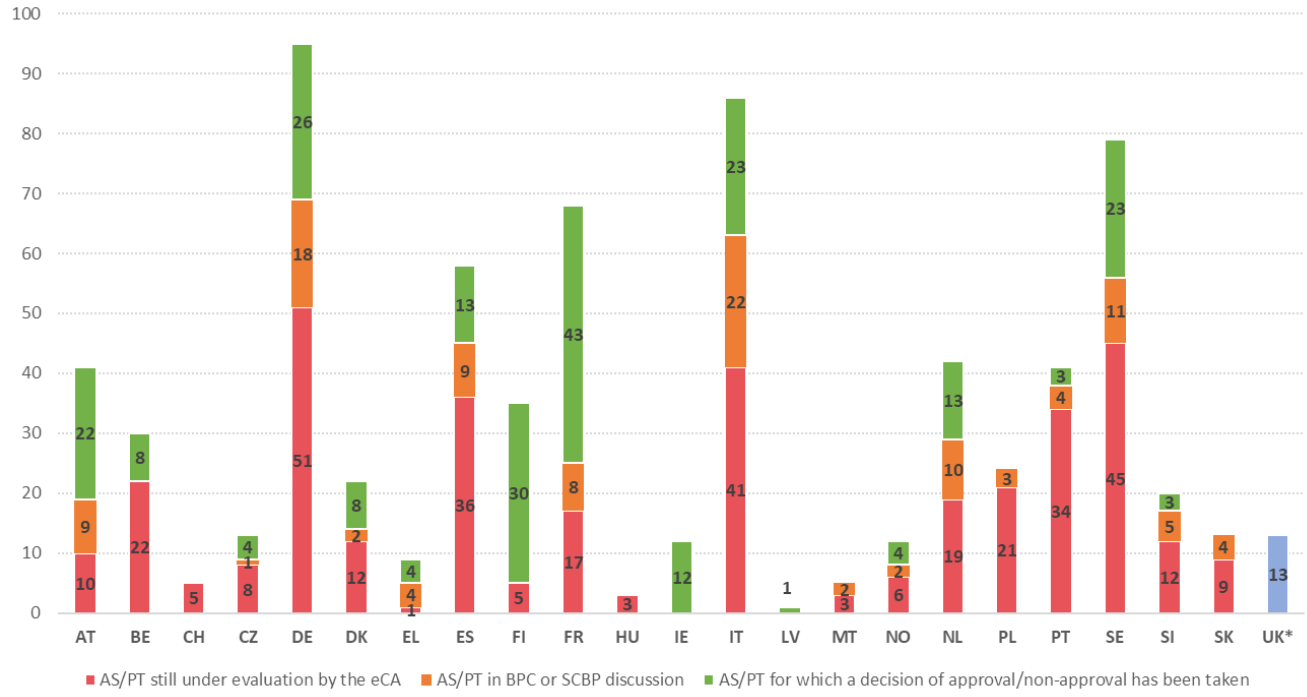
When considering only the 1st priority list (with a deadline for submission of the assessment report of 31 December 2015), the best performers are Finland, Ireland, Norway and the Netherlands, who delivered all the assessment reports, and the worst performers are the

Czech Republic, Belgium and Spain, with 20% or more of the active substance/product-type combinations still under evaluation[28].

For the 2nd priority list (with a deadline for submission of the assessment report of 31 December 2015) the best performers are Ireland and Norway, who delivered all the assessment reports and the worst performers are Belgium, Spain and Portugal, with more than 50% of the active substance/product-type combinations still under evaluation.

For the 3rd priority list (with a deadline for submission of the assessment report of 31 December 2018) the best performers are Ireland and Latvia, who submitted all the assessment reports, and the worst performers are Hungary, Poland, Portugal and Slovenia, with more than 70% of the active substance/product-type combinations still under evaluation.

Finally, for the 4th priority list (with a deadline for submission of the assessment report of 31 December 2019), the best performer is Finland, who submitted all the assessment reports, while Belgium, Germany, Italy, Malta, Portugal, Sweden and Switzerland have not yet submitted any of the assessment reports.



*(for the UK it corresponds to dossiers for which decisions were taken, as the other dossiers still under assessment or peer review were transferred to other MS)

Figure 3.3 Performance of Member States for all priority lists

Delays in the submission of the assessment reports can be attributed to lack of resources allocated in Member States, delays of applicants in submitting additional data, complex technical questions on specific dossiers that need to be resolved first, evolution of technical

[28] It has to be noted that some delays are related to recent applications due to inclusion of some food and feed active substances combinations in the Review Programme in 2018 for product-type 19.

guidance, and the adoption of new scientific criteria[29] for the determination of endocrine-disrupting properties, which triggered the need for further data and further assessments.

The first ECHA BPC opinions on active substances in accordance with Article 8(4) of the BPR were delivered in April 2014. The number of opinions delivered by the BPC shows a decrease from 2016 onwards, with the lowest number of opinions (3) delivered in 2019 (see Figure 3.4). In total, 163 BPC opinions were delivered until 31 December 2019, representing 54% of the total expected opinions based on the target established in 2013.

This is directly correlated with the delays of Member States in delivering the CARs or conducting further work emanating from the peer review of their CARs.

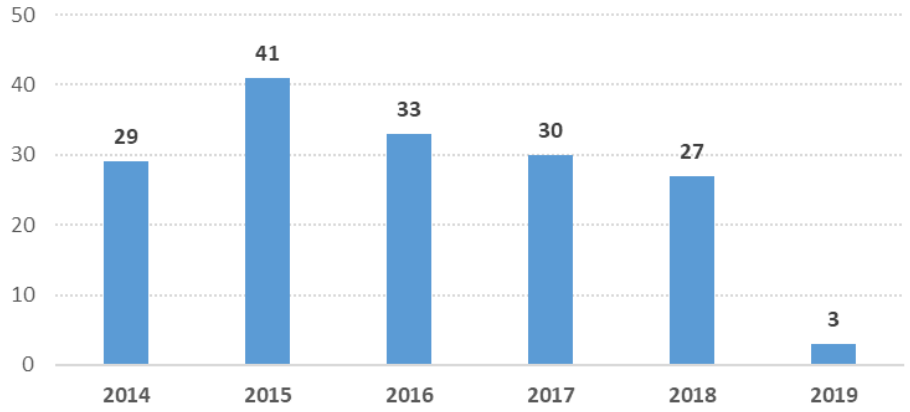


Figure 3.4 Number of BPC opinions on existing active substances

The evolution of the number of decisions adopted by the Commission on approval/non-approval of active substances[30] follows the same trend as the number of BPC opinions provided to the Commission. Figures 3.5 and 3.6 show the evolution of the number of Commission decisions on approval/non-approval and the number of active-substance/product-type combinations covered by these decisions, respectively. While the number of decisions adopted between September 2013 and 2016 increased steadily, a significant decrease occurred in 2017 and 2018, with a small increase again in 2019.

[29] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council (OJ L 301, 17.11.2017, p. 1–5)

[30] The Commission decision on approval/non-approval is in general adopted 6-9 months after the adoption of the respective BPC opinion(s).

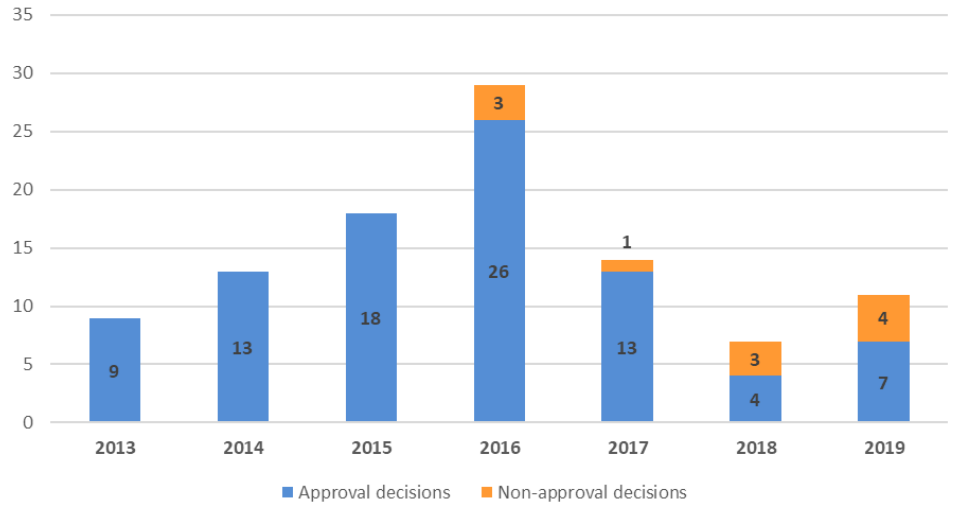


Figure 3.5: Number of decisions on approval/non-approval adopted by the Commission for an active substance covering one or more product-types

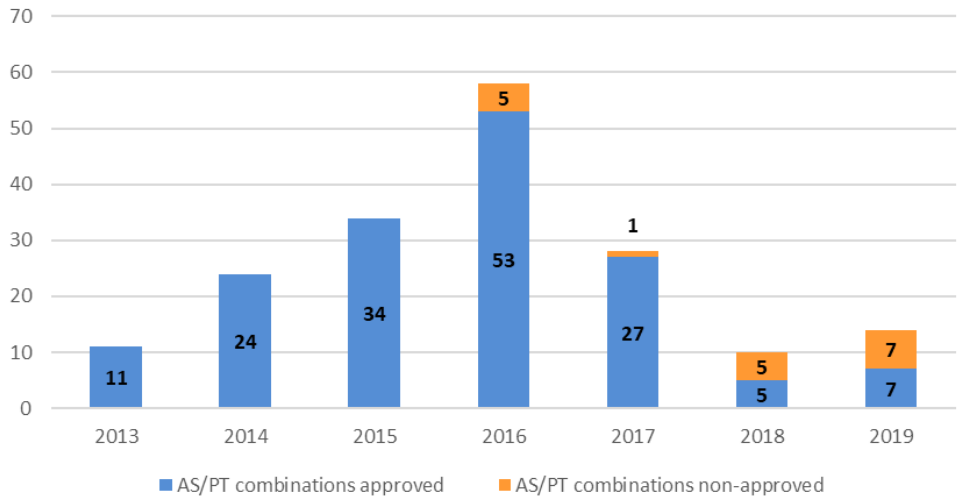


Figure 3.6: Number of active substance/product-type combinations covered by Commissions decisions on approval/non-approval

Figure 3.7 illustrates the cumulative number of decisions adopted by the Commission in terms of active substance-product-type combinations covered by those decisions.

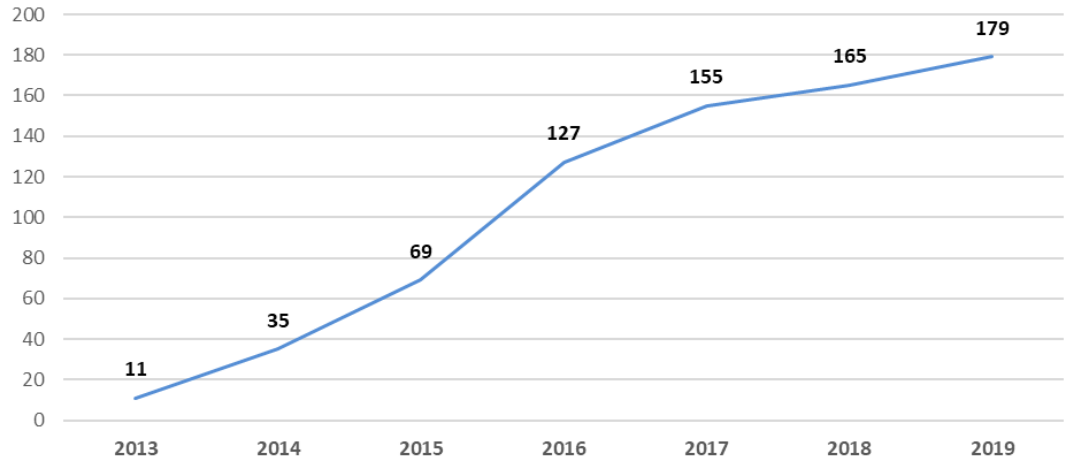


Figure 3.7: Cumulative number of active substance/product-type combinations covered by Commissions decisions on approval/non-approval

As a consequence of the significant delays in the evaluation of the applications by Member States, progress in the completion of the Review Programme on 31 December 2019 has been much slower than expected. Even for the first priority list for which the evaluating Member States had to submit their CARs to ECHA by 31 December 2015 only 77% of the work has been finalised. For that priority list, 21 active substances are still under evaluation by the evaluating Member States (in Austria, Belgium, Czech Republic, France, Germany, Greece, Portugal, Spain, Sweden, and one application in Switzerland)[31]. For the four first lists of the review programme for which all draft assessment reports should have been submitted during the period covered by this report, almost all Member States have not submitted on time their draft assessments for one or more dossiers, some Member States having still many dossiers under evaluation. The work related to the Review Programme has been completed only in two Member States that were evaluating a relatively low number of active substances (Ireland and Latvia). As shown in Figure 3.8, apart from the first priority list, the percentages of completion of the Review Programme for each list are still very low, which is exacerbated by the fact that most evaluations started between 2004 and 2008 (i.e. more than 10 years ago).

[31] It has to be noted that some delays are related to recent applications due to inclusion of some food and feed active substances combinations in the Review Programme in 2018 for product-type 19.

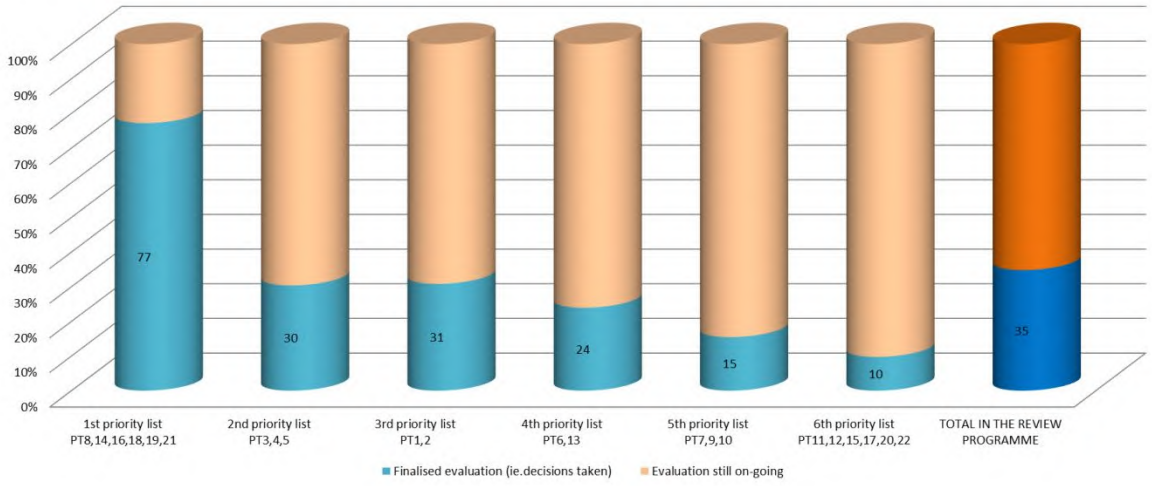


Figure 3.8: Progress on the Review Programme per priority lists (in percentage) on 31 December 2019

3.1.1. Backlog reports

Around 150 draft assessment reports were already submitted by the eCAs for peer review on 1 September 2013 when the BPR came into application (usually referred to as "backlog reports"). At the beginning of the implementation of the BPR, a work plan was set up with ECHA and Member States in order to complete the peer review of these active substances within 3 years (in line with the objective of 50 opinions per year)[32]. Pursuant to the transitional provisions set up under Article 90(2), for these dossiers the Commission must base its decision on the criteria established by the BPD, which among other differences, did not contain exclusion criteria as now set out in Article 5 of the BPR or substitution criteria as now set out in Article 10 of BPR.

However, despite this intention, on 31 December 2019, the peer review has been completed and decisions have been taken on only two thirds of these backlog dossiers, while 47 reports from 12 Member States (Denmark, France, Germany, Greece, Italy, Malta, the Netherlands, Portugal, Spain, Sweden, Slovakia) were still under peer review on 31 December 2019[33]. For some of these reports supportive actions from the evaluating competent authorities are needed to make progress on the peer review, or further information requested from applicants is not yet submitted.

3.1.2. Withdrawal and taking over

In accordance with Article 11 of the Review Programme Regulation, participants in the Review Programme may withdraw their support for an active substance/product-type combination for which they had submitted an application for approval. When that occurs, ECHA publishes an invitation to prospective applicants to take over the role of participant, unless that opportunity has already been granted once as provided for by Article 14 of the

[32] Work plan available at: https://circabc.europa.eu/w/browse/d46486e0-e951-4292-9101-086157ef413b

[33] Tracking report available at: https://circabc.europa.eu/w/browse/0e0cd459-7226-4f8b-8459-b27d12434b70

same Regulation. In case of redefinitions of active substances, an invitation to take over the role of participant is also published by ECHA.

In 2014, the Commission published a list[34] of 88 active substance/product-type combinations no longer supported, for which interested companies could make a notification and take over the role of participant. 8 of these active substance/product-type combinations were taken over. Between 2013 and 2019, ECHA published invitations to take over the role of participant for 140 active substance/product-type combinations. Of those 140 active substance/product-type combinations, 77 were taken over by new participants. Figure 3.9 shows the number of active substance/product-type combinations covered by the invitations published from 2013 to 2019 and the number of active-substance/product-type combinations taken over[35] by other participants following the publication of the invitations.

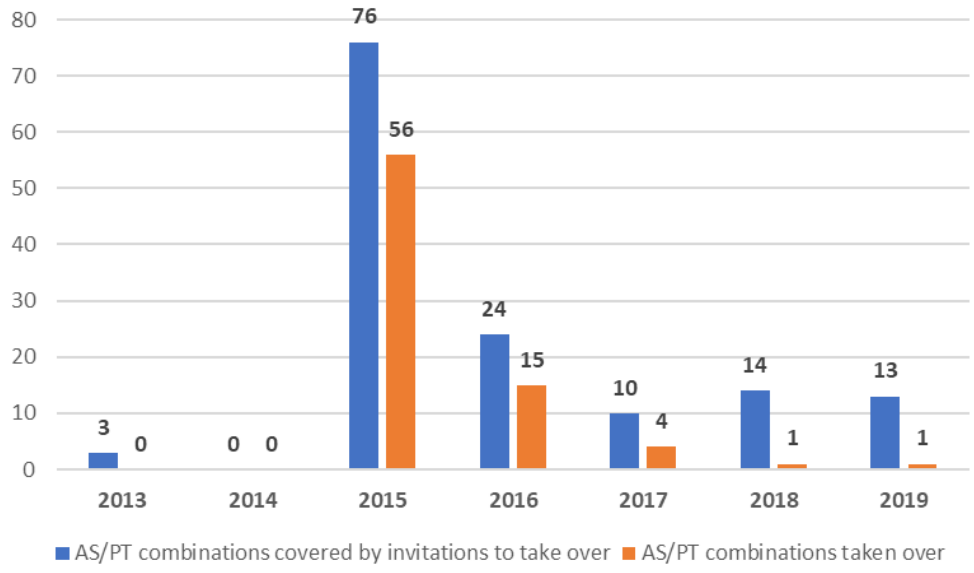


Figure 3.9: Number AS/PT combinations for which an invitation to take over the role of participant was published and number of AS/PT combinations taken over

The continuous significant delays in the evaluation of active substances led the Commission to take action. In 2015 it sent letters to all Member States, highlighting the importance of completing the Review Programme, as main objective which underpins all other objectives of the BPR, and inviting them to ensure that competent authorities have the appropriate resources to fulfil their obligations under the BPR. In 2017 the Commission initiated discussions with all parties involved in the process (Competent Authorities, ECHA, industry associations) in order to better understand the main causes of the delays, to identify possible actions to minimise such delays, and renew the commitment from Member States in completing their tasks. A list of actions[36] to be undertaken by applicants, Member States,

[34] Part 2 of Annex II to Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council.

[35] The taking over occurs 12 months after the publication of the invitation, as prospective applicants have 12 months to notify their interest to take over.

[36] Available at https://circabc.europa.eu/w/browse/f5b309a8-abef-4550-a4c7-fe14a67f2c13

ECHA and the Commission was discussed in various meetings of Competent Authorities and eventually agreed in March 2018.

ECHA also conducted a survey addressed to Competent Authorities in 2018 in order to identify the causes for delays and propose solutions. ECHA organised a workshop on the active substance approval process in February 2019, with a special focus on the Review Programme. In light of the survey results and of the information collected at the workshop, ECHA proposed an Action Plan[37] aiming to advance progress on the Review Programme, which was agreed by the Commission and Member States' Competent Authorities in February 2020. In the context of the Action Plan, ECHA is closely cooperating with Member States, providing support beyond its initially foreseen role in the BPR.

Apart from having insufficient resource and delays by the applicants in submitting additional information required by the evaluating Member State during the evaluation, one of the factors highlighted by Member States as cause for recent delays in their evaluation of active substances was the requirement to perform the assessment of endocrine disrupting properties according to the scientific criteria which the Commission adopted as required by Article 5(3) of the BPR[38] and applicable since June 2018. According to the specific actions included in the Action Plan, ECHA is providing Member States specific further advice and guidance related to this assessment.

Status of Review Programme at the end of the reporting period

On 31 December 2019, 474 active substance-product/type combinations of the Review Programme were still under examination, of which 360 (76%) still under evaluation in Member States and 114 (24%) under peer review at ECHA level, while the work was completed for 252 active substance-product/type combinations. Thus, five years before the current deadline of 31 December 2014 to complete the review programme started in 2004, only 35% of the work programme had been completed.

3.2. Active substances outside the Review Programme

3.2.1. Existing active substances outside the Review Programme

For some active substances identified as existing active substances, initially no company or Member State expressed an interest to support them, therefore those active substances were not included in the Review Programme[39], or they were included only for specific product-types. However, applications for approval of these substances can be submitted under the BPR.

Applications for 68 existing active substance/product-type combinations outside the Review Programme were submitted in the reporting period. 8 decisions on the approval/non-approval

[37] Available at https://circabc.europa.eu/w/browse/9b8a5c0c-9d25-4373-b89f-8ddfeeabe2e8

[38] Commission Delegated Regulation (EU) 2017/2100 of 4 September 2017.

[39] For instance cholecalciferol, allyl isothiocyanate, benzyl alcohol.

were adopted, covering 8 active substance/product-type combinations. Of these, seven decisions approved the active substance/product-type combinations (Figure 3.10).

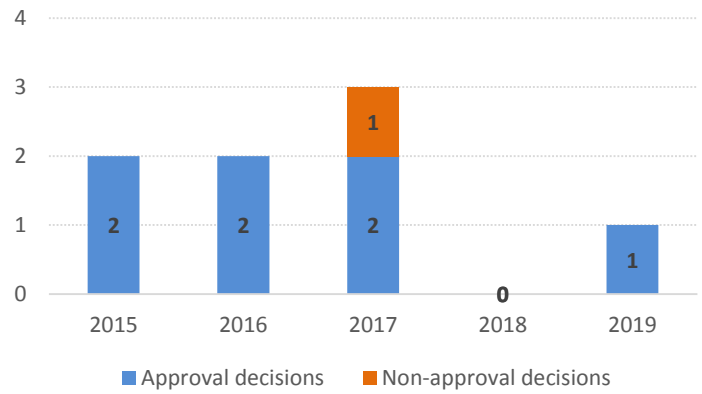


Figure 3.10: Number of decisions on approval/non-approval of existing active substances outside the Review Programme

3.2.2. New active substances

Active substances not on the market in a biocidal product on 14 May 2000 are considered as new active substances. In order to be able to place them on the market, companies have first to apply for approval by submitting a dossier to ECHA. After ECHA has accepted the application as set out in Article 7(2) of the BPR, the evaluating competent authority of a Member State chosen by the company carries out a completeness check and, when finding the dossier complete, has to conduct an evaluation within one year. As for existing active substances, the CAR is forwarded to the Biocidal Products Committee of the Agency, which prepares an opinion within 270 days. The opinion serves as the basis for the decision of the Commission on approval (or not) of the active substance. In the meantime, it is not possible to make available and use in the EU such active substances in biocidal products. Provisional authorisations may be granted in certain cases until a decision on the approval of the active substance is adopted, as indicated in section 4.8(ii) of this document.

10 new active substances were evaluated since the entry into application of the BPR, 9 of which were approved, while one was not approved. Of the 9 new active substances approved (covering 13 active substance/product-type combinations) 5 are used in preservatives (product-types 7, 8, 9, 10), 2 are used in insecticides and 2 are used in anti-fouling products. 3 of them are candidates for substitution and, therefore, were approved for 7 years only. One of the approved new active substances is a micro-organism[40] used in the preservation of construction materials (product-type 10). The new active substance not approved is also micro-organism[41] intended to be used as preservative in industrial processing water systems (product-type 11). Applications related to 6 other new active substances, covering 10 active substance/product-type combinations are still under assessment.

[40] *Pythium oligandrum* strain M1.

[41] *Willaertia magna* c2c Maky. A new application for approval for product-types 11 and 12 has been submitted in the meantime.

Figure 3.11 illustrates the number of Commission decisions related to new active substances adopted during the reporting period with respect to the number of active substance/product-type combinations covered.

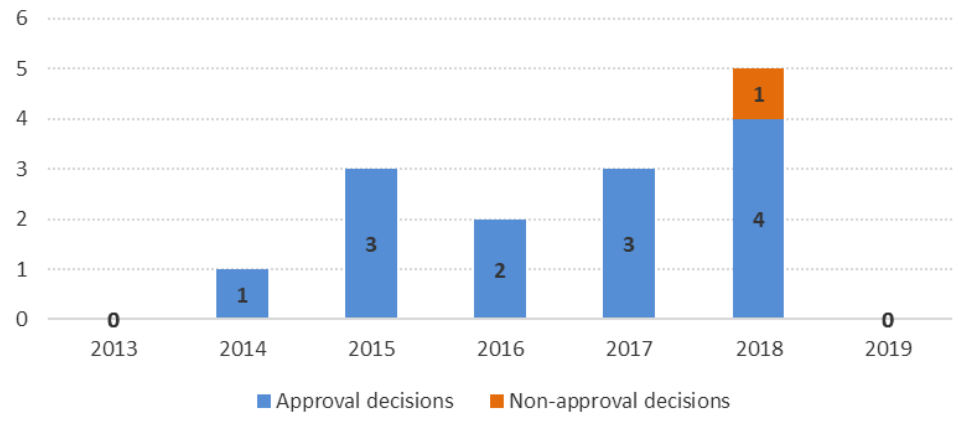


Figure 3.11: Number of active substance/product-type combinations covered by Commission Decisions approving/non-approving new active substances

For five of the approved new active substances the approval procedure followed the deadlines set in the Regulation without major delays and the decision to approve them was adopted within three years from the submission of the application (3.5 years in one case). However, for three of them the delays were more significant (the approval was granted after more than six years from the submission of the application) - in two of these cases the evaluating Member State performed the evaluation in five years or more from the completeness validation. For the other, the CAR was submitted 2 years after the submission of the application but the peer-review took 4.5 years. Overall, the performance of the evaluating Member States for new active substances is thus somewhat better than for existing active substances under the Review Programme, albeit with large divergences.

3.3. Active substances which are micro-organisms

Micro-organisms are alternatives to chemical active substances and are expected to have less harmful effects on human health, animal health and/or the environment.

So far, six active substances consisting of micro-organisms have been approved under the BPR, of which four[42] for use in insecticides, one[43] for use in veterinary hygiene disinfecting products and one[44] for use as construction material preservative. One micro-organism[45], expected to be used in repellents or attractants, has been included into Annex I to the BPR.

[42] *Bacillus thuringiensis* subsp. *israelensis* serotype H14 AM65-52, *Bacillus thuringiensis* subsp. *israelensis,* strain SA3A, *Bacillus sphaericus* 2362 ABTS-1743, *Bacillus thuringiensis* subsp. *kurstaki* ABTS-351.

[43] *Bacillus amyloliquefaciens* strain ISB06.

[44] *Pythium oligandrum* strain M1.

[45] *Saccharomyces cerevisiae.*

No other micro-organism is included in the Review Programme. An application for approval of a new active substance which is a micro-organism[46] is under assessment.

3.4. Exclusion and substitution criteria

In order to achieve a high level of protection of human and animal health and the environment, the BPR introduced the so-called 'exclusion criteria' and 'substitution criteria'.

Exclusion criteria

Active substances meeting the exclusion criteria, which are based on intrinsic properties of the substance considered of particularly high concern to human health or the environment, can in principle not be approved for use in biocidal products. These include:

- classification as carcinogen, mutagen or toxic to reproduction, categories 1A or 1B, according to the CLP Regulation[47]
- endocrine disrupting properties with respect to humans on the basis of the criteria established in Regulation (EU) 2017/2100 or identified as endocrine disruptor in accordance with the REACH Regulation
- persistent, bioaccumulative and toxic (PBT) properties, or very persistent and very bioaccumulative (vPvB) properties.

Possibilities for derogation to exclusion are foreseen in Article 5(2) of the BPR on grounds of negligible risks from exposure to the substance, essentiality of the substance to prevent or control a serious danger to human health, animal health or the environment, or disproportionate negative effect for society that a non-approval would cause when compared to the risks caused by the use of the active substance. In all cases, the availability of suitable and sufficient alternative substances or alternative techniques is a key consideration. In case a derogation possibility applies, the approval of the active substance is granted for a period of maximum five years.

So far, 3 active substances meeting exclusion criteria, covering 3 active substance/product-type combinations were not approved, due to due to the identification of unacceptable risks related to their use. 21 active substances meeting the exclusion criteria have been approved, covering 24 active substance/product-type combinations. 17 of these active substance/product-type combinations were approved before the entry into application of the BPR and 7 were approved under the BPR, either following the transitional rules as set out under Article 90(2) of the BPR when the CAR was submitted by the evaluating Member States prior to 1 September 2013, or after a thorough examination of the derogation possibilities when the CAR was submitted by Member States after 1 September 2013. Among the 21 approved active substances, 10 are rodenticides[48] (one them is a new active

[46] *Trichoderma harzianum* strain T-720, for use as wood preservative.

[47] Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1–1355).

[48] Difethialone, difenacoum, coumatetralyl, bromaniolone, chlorophacinone, flocoumafen, warfarin sodium, brodifacoum, warfarin, cholecalciferol.

substance[49]; for one of them, the approval expired in 2017[50]), while the others are active substances for use in preservatives, especially wood preservatives[51].

Substitution criteria

Article 10 of the BPR lays down the criteria which qualify an active substance as candidate for substitution (and they include those substances that meet one or more of the exclusion criteria but may be approved according to the derogation possibilities mentioned above). The aim of this provision is to identify substances which despite not meeting the exclusion criteria are still of particular concern to public, animal health or the environment and to ensure that these substances are phased-out and replaced by more suitable alternatives over time.

If, during the assessment of an application for approval, an active substance is identified by the evaluating competent authority as potentially meeting any of the criteria, ECHA has to initiate a public consultation during which interested third parties may submit relevant information, including on available alternatives. The input received during the public consultation has to be taken into consideration when ECHA's BPC finalises its opinion on the active substance. The designation as a candidate for substitution has two consequences: (i) a shorter approval period (maximum of seven years) and (ii) requirement for competent authorities to carry out a comparative assessment when applications for authorisation of products containing them are submitted.

So far, the participation to the public consultations was limited and/or the BPC did not reach a clear conclusion on availability of alternatives. 4 active substances meeting the substitution criteria, covering 9 active substance/product-type combinations were not approved, due to the identification of unacceptable risks related to their use. 20 active substances meeting the substitution criteria have been approved (other than active substances meeting the exclusion criteria and approved under the derogation possibilities), corresponding to 37 active substance/product-type combinations. The approved active substances are used in disinfectants, preservatives, insecticides or antifouling products. 26 of these active substance/product-type combinations were approved since the entry into application of the BPR.

3.5. Renewal of active substance approval

Applications for renewal of approval of an active substance must be submitted by interested companies to ECHA at the latest 1.5 years before the expiry of the approval. The evaluating competent authority (eCA) has to decide, based on the information available in the application and in light of current scientific knowledge, whether a full evaluation is necessary. Although flexibility exists in the BPR as to the choice of the eCA for renewal, for efficiency reasons and in order to ensure a level of guarantee to applicants that a competent authority will be willing to act as eCA, Member States agreed[52] that the eCA for the renewal should be the same as for the original approval, unless a change of eCA is mutually agreed

[49] Cholecalciferol.

[50] Warfarin sodium.

[51] For instance thiacloprid, propiconazole, disodium tetraborate, boric acid, creosote, cyproconazole.

[52] Note agreed by Member States' Competent Authorities for Biocidal Products, https://circabc.europa.eu/w/browse/c7442864-5851-4710-936e-fad2491b835e

between the original and the new eCA (and with the prospective applicant's agreement whenever possible). If the evaluating competent authority decides that a full evaluation is not necessary, it has to provide to the BPC a recommendation on the renewal of approval within 180 days. If a full evaluation is necessary, the assessment report and the recommendation have to be provided within 365 days from the acceptance of the application.

The BPC must adopt an opinion within 270 days of the recommendation being submitted in the case of a full evaluation, or within 90 days, if a full evaluation was not necessary. This opinion serves as a basis for decision by the Commission. The renewal of approval of an active substance may be granted for a maximum period of 15 years for all product-types concerned. However, when an active substance meets the exclusion or the substitution criteria, the approval may be renewed for a period of maximum 7 years.

By 31 December 2019, 19 applications for the renewal of approval of active substances had been submitted, of which 8 concerned anticoagulant rodenticide active substances. Figure 3.12 shows when the applications for renewal of approval were submitted.

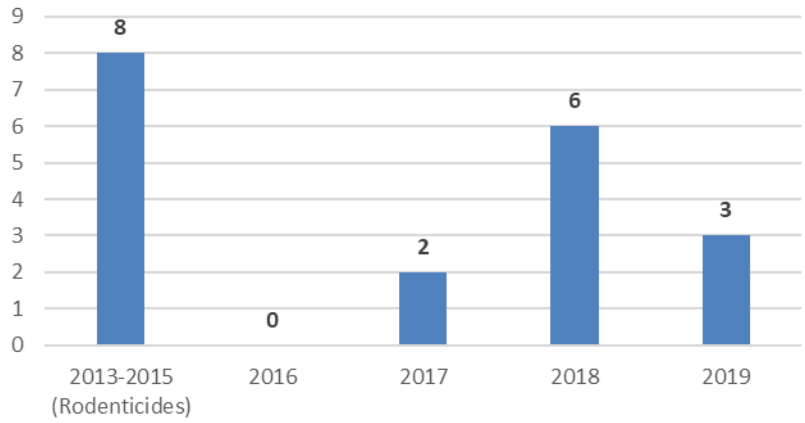


Figure 3.12: Submissions of applications for renewal of approval of active substances

The applications for renewal of anticoagulant rodenticides were submitted between 2013 and 2015. The evaluation of all these applications was conducted in a coordinated manner in order to facilitate synergies in the review and comparison of the risks and benefits of these active substances, as well as of the risk mitigation measures applied to them. The related CARs were submitted by Member States in 2016 and the BPC opinions were adopted in June 2016. The respective Commission decisions on the renewal were adopted in July 2017, granting a period of renewal of approval of seven years.

The other 11 applications for renewal were submitted between 2017 and 2019. For none of them the CAR has been submitted to date.

For eight active substances, no application for renewal of approval has been submitted. This concerns mostly active substances meeting the exclusion or substitution criteria (warfarin sodium for rodenticides; dichlofluanide, thiacloprid, clothianidin, thiametoxam, thiabendazole, fenpropimorph, tolylfluanid, cyproconazole for wood preservatives).

Pursuant to Article 14(5) of the BPR, where for reasons beyond the control of the applicant the approval of the active substance is likely to expire before a decision has been adopted on

its renewal, the Commission shall adopt decisions postponing the date of expiry of the active substance approval for a period sufficient to enable it to examine the application.

So far, the Commission adopted 10 decisions postponing the expiry date of approval, related to 15 active substances, of which 8 rodenticides, 6 wood preservatives and 1 insecticide. These became necessary in all cases except for the rodenticides, due to decisions by the respective evaluating competent authority to perform a full evaluation and due delays in the evaluations of the applications. The extension decisions related to rodenticides were also needed in order to allow for the simultaneous assessment at renewal of all anticoagulant rodenticide active substances, as explained above.

Table 3.2 indicates the number of extension decisions adopted each year by the Commission and the active substances covered by the decisions.

Year of decision postponing the expiry of approval	*Number of decisions adopted*	*Active substances covered by the decisions*
2014	1	Difethialone PT 14 Difenacoum PT 14
2015	1	Bromadiolone PT 14 Chlorophacinone PT 14 Coumatetralyl PT 14
2016	1	Flocoumafen PT 14 Brodifacoum PT 14 Warfarin PT 14
2017	1	Creosote PT 8
2018	1	Sulfuryl fluoride PT 8
2019	5	IPBC PT 8 Tebuconazole PT 8 K-HDO PT 8 Etofenprox PT 8 Indoxacarb PT 18

Table 3.2 Commission Decisions postponing the date of expiry of active substance approval

4. BIOCIDAL PRODUCT AUTHORISATION

As a general principle under the BPR, biocidal products need to be authorised before they can be made available on the market. The active substance(s) they contain need to have been approved first. Several options for product authorisation[53] are available to companies, depending on the active substance(s) contained in the product and the number of Member States in which companies intend to make the product available:

- National authorisation, referred to in Chapter VI (Articles 29 to 31) of the BPR, which provides for the authorisation in a Member;
- Mutual recognition of national authorisations in several Member States either at the same time or sequentially, referred to in Chapter VII (Articles 33 to 39) of the BPR Regulation;
- Union authorisation, valid in all Member States, referred to in Chapter VIII (Articles 41 to 46) of the BPR;
- Simplified authorisation, referred to in Chapter V (Articles 25 to 28) of the BPR, which provides for an accelerated authorisation procedure for products containing only active substances included in Annex I to the Regulation.

The BPR foresees also circumstances in which it is possible to derogate from the general principle mentioned above (see section 4.1.4).

4.1. National authorisation

National authorisation is the most suitable type of authorisation if a company intends to make the product available only in one Member State. As provided for by Articles 29 and 30 of the BPR, the application for authorisation has to be submitted to the competent authority of that Member State, which evaluates the application and makes a decision on the authorisation within 365 days. Authorisation may be granted for a single biocidal product or a biocidal product family. National authorisation for a biocidal product can be granted for a maximum of 10 years and is renewable. For biocidal products containing an active substance which is a candidate for substitution, national authorisation may be granted for a period not exceeding five years. In any case the authorisation cannot remain valid for longer than the approval period of the active substance(s) contained therein.

The application for authorisation of a biocidal product already available on the market under the transitional provisions of Article 89 must be submitted by the date of approval of the active substance, as such a product cannot be made available any longer after 180 days from the date of approval of the active substance and existing stocks must be removed from the market 365 days after the approval date, as set out in Article 89(3) of the BPR. Applications for authorisation can also be made at a later date, but until the authorisation is granted, the product cannot be made available on the market and cannot be used.

Between 2013 and 2019, 2,642 biocidal products were authorised in the Member States by national authorisation in accordance with the BPR. Figure 4.1 shows the number of products

[53] Further information on the product authorisation procedures is available at https://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products

authorised in each Member State. The highest number of products was authorised France (334), followed by the UK (318), Italy (252) and Spain (238).

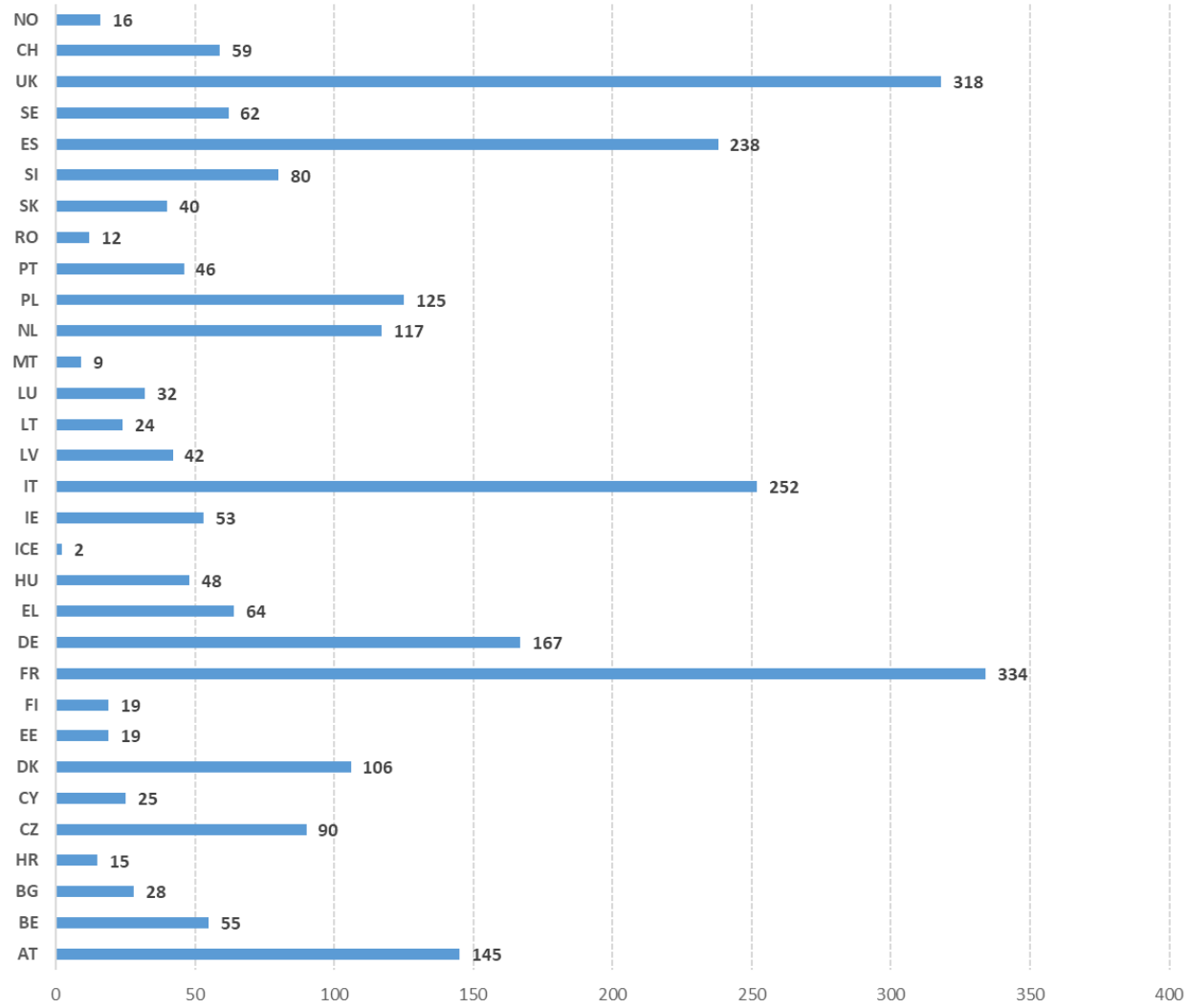


Figure 4.1: Number of products authorised by national authorisation in each Member State

Figure 4.2 illustrates the number of products authorised by national authorisation in accordance with the BPR in all Member States every year.

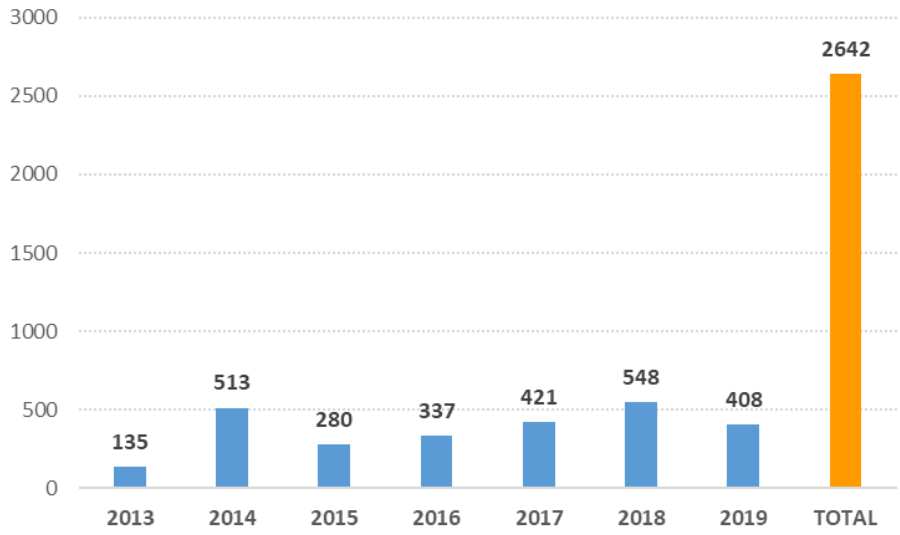


Figure 4.2: Overall number of products authorised by national authorisation per year

Of the products authorised by national authorisation in all Member States, 64% (1,698) are single biocidal products and 36% (944) are members of biocidal products families.

4.2. Mutual recognition

If a company wishes to place the same product on the market in more than one Member States, it has the option to apply in those other Member States for recognition of an authorisation granted by one Member State acting as so-called reference Member State. The provisions concerning mutual recognition aim to avoid duplication of the evaluation procedures and to ensure free movement of biocidal products within the Union. Two procedures are available:

- Mutual recognition in sequence (Article 33 of the BPR): after national authorisation in one Member State (the reference Member State), the authorisation holder applies in other Member States (the Member States concerned) to recognise the authorisation and authorise the product;
- Mutual recognition in parallel (Article 34 of the BPR): the applicant submits an application for authorisation in one Member State (the reference Member State) and at the same time applies in other Member States (the Member States concerned). The concerned Member States participate in the evaluation conducted by the reference member States and all must eventually authorise the product at the same time in accordance with the agreed assessment.

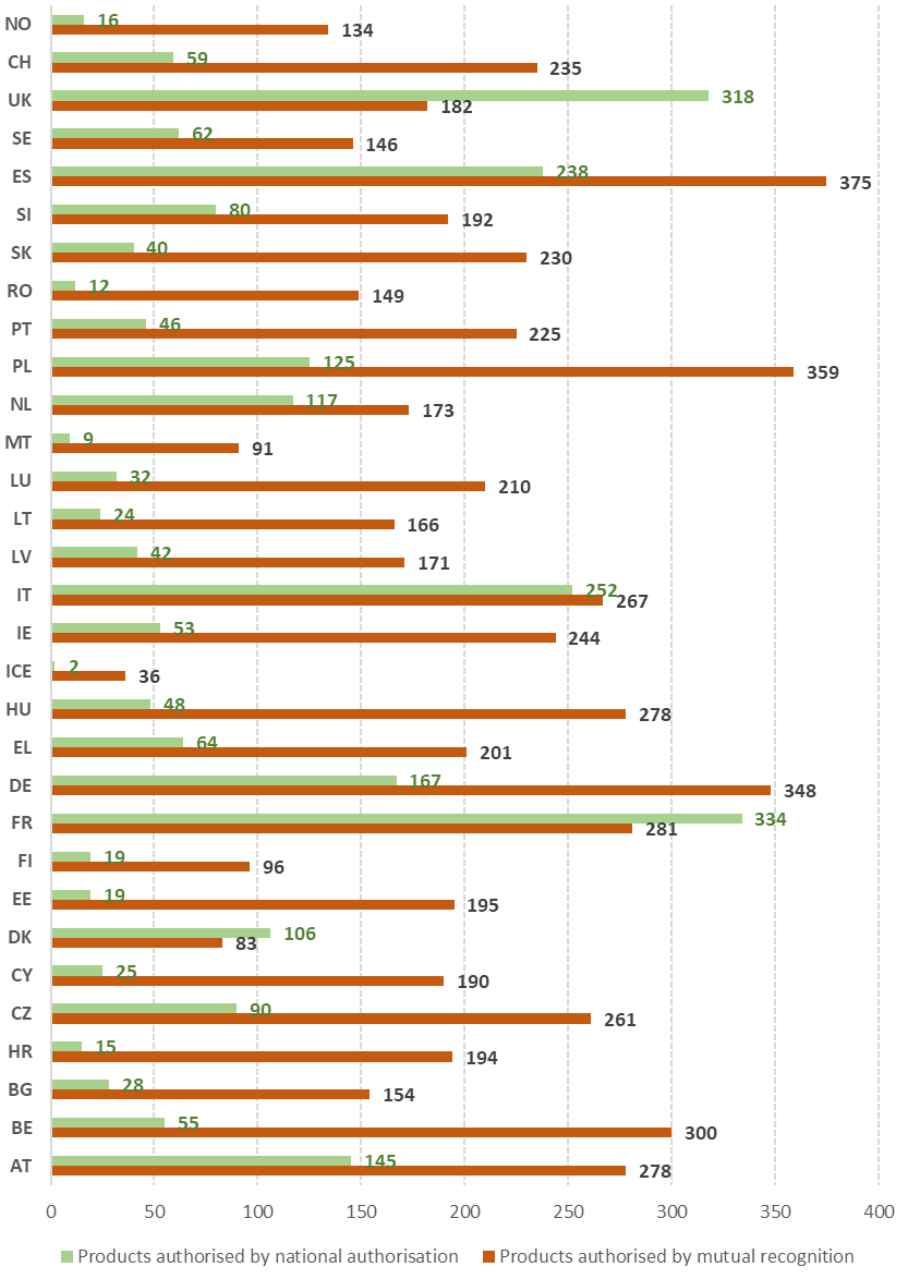


Figure 4.3 Number of products authorised by mutual recognition and standalone national authorisation

Figure 4.3 illustrates the number of products authorised in each Member States by mutual recognition and the comparison with the number of products authorised by national authorisation.

In most Member States, EEA States and Switzerland (28 out of 31) the majority of products authorised on the national market were authorised following mutual recognition procedures. Overall in the Member States, authorisation by mutual recognition was granted for 6,444 products, which is almost twice as many as products authorised by standalone national authorisation (see Figure 4.4). Of the 6,444 products authorised by mutual recognition, 42% (2,724) are members of biocidal products families.

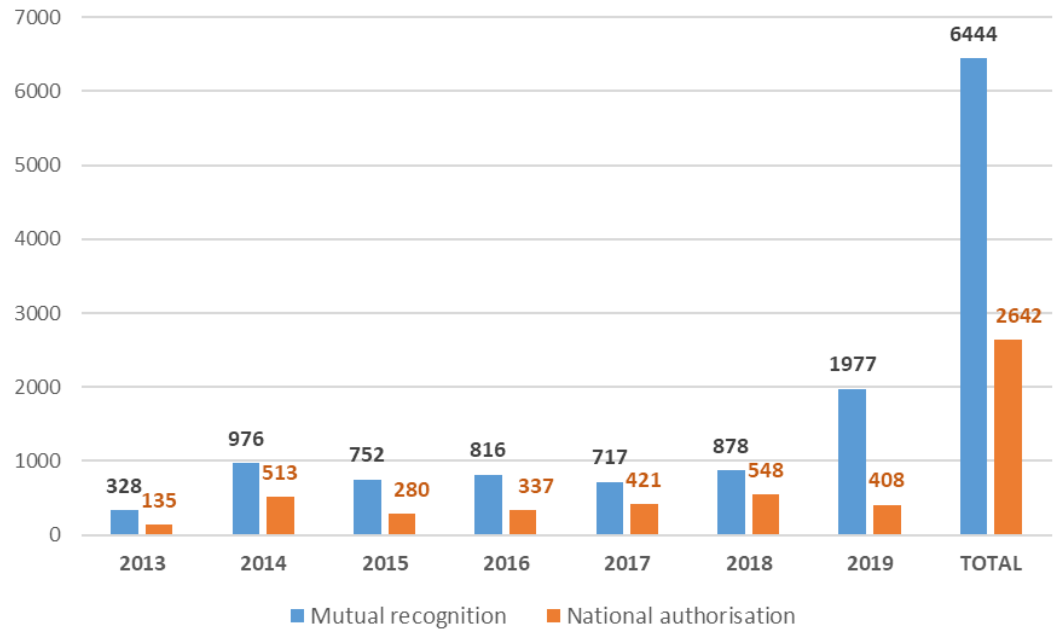


Figure 4.4: Number of products authorised by mutual recognition in all Member States and number of products authorised by national authorisation

Based on the data available[54], there are significant delays with respect to the legal timelines set out in the BPR for all biocidal product authorisation procedures initiated between 2010 and 2020. The largest delays were registered in mutual recognition procedures, especially mutual recognition in parallel. On average, in all Member States, 63% of the procedures for mutual recognition in sequence were delayed, and 72 % of the procedures for mutual recognition in parallel. In 18 Member States the latter percentage is higher than 80%.

Disagreements during mutual recognition process

Disagreements between Member States may arise during the mutual recognition process, with regard to the conclusions of the technical assessment performed by the reference Member State, or with regard to the summary of product characteristics. Points of disagreement are to be referred to the Coordination Group set up under of Article 35 of the BPR, which should try to find an agreement on the action to be taken. The Coordination Group is composed of representatives of Member States and of the Commission, and the secretariat is provided by ECHA. In the absence of an agreement between Member States within 60 days, the disagreement is referred in accordance with Article 36 of the BPR to the Commission, which takes a final decision by means of an implementing act.

The Coordination Group has thus a key role in harmonising product authorisations. So far 180 referrals were submitted to the Coordination Group (see Figure 4.5) and agreement could be found for 158 (87%). Figure 4.6 indicates the number of referrals initiated by the specific Member States.

[54] Available at https://circabc.europa.eu/w/browse/a5982814-9d5e-4279-83b1-32ff42fa0792

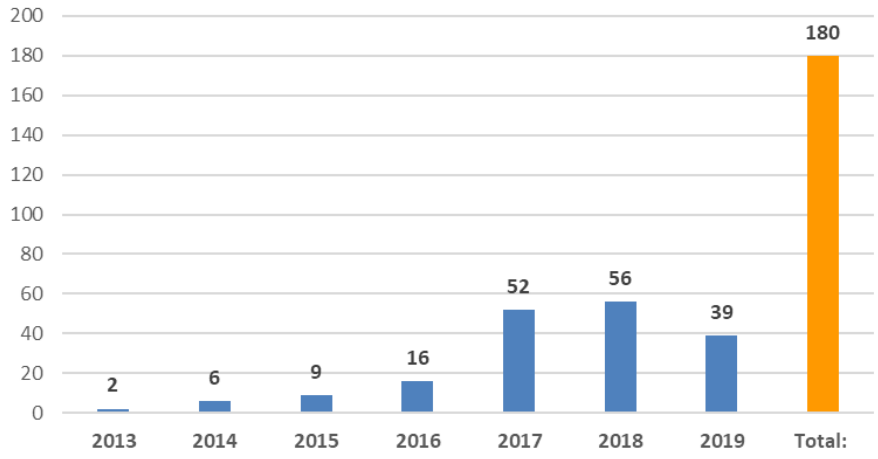


Figure 4.5: Number of referrals to the Coordination Group

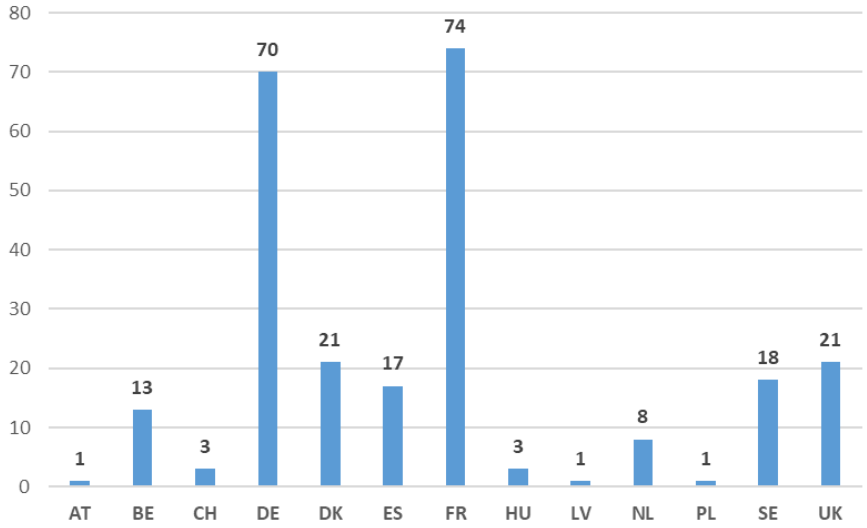


Figure 4.6: Number of referrals initiated* by Member States
*For some referrals there were more than one initiating Member State; those referrals are counted in more than once

Only 15 (8%) of the referrals resulted in disagreement and were referred to the Commission (see Figure 4.7).

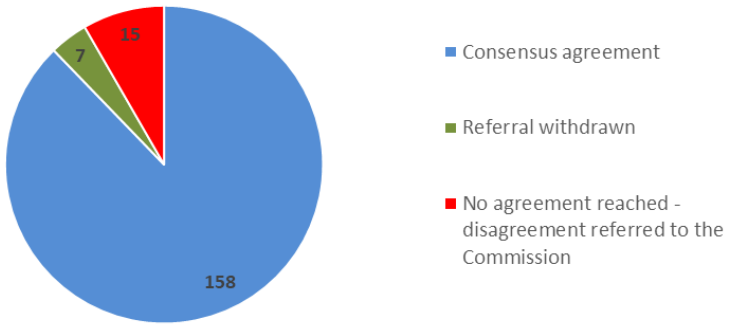


Figure 4.7: Number of referrals – agreement reached, disagreement referred to the Commission and referrals withdrawn

For seven cases referred to it, the Commission adopted decisions.

Derogation from mutual recognition

Authorisations according to mutual recognition in parallel or in sequence should be granted under the same terms and conditions in all involved Member States. However, in certain cases indicated in Article 37 of the BPR (e.g. protection of health and life of humans or animals, protection of the environment, public security), any of the concerned Member States may propose to adjust the conditions of the authorisation to be granted or refuse to grant an authorisation. A justification for the derogation needs to be communicated to the applicant and an agreement with the applicant on the proposed derogation needs to be sought.

Altogether 10 Member States reported data related to the number of such derogations. Among these, Spain reported the highest number of derogations (177), followed by Belgium (77). In most Member States an increase in the number of these derogations occurred between 2017 and 2019.

If the Member State concerned cannot reach an agreement with the applicant on the proposed derogation, the matter is referred to the Commission, which takes a final decision on the derogation. Since the entry into application of the BPR four cases were referred to the Commission and in all cases the Commission decision confirmed that the derogation proposed by the concerned Member State to the applicant was justified in accordance with the grounds included in Article 37(1).

4.3. Union authorisation

The BPR newly introduced the possibility for Union-wide authorisation of a biocidal product. As set out in Article 42 of the BPR, a Union authorisation may be granted by the Commission for 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 (the so-called "pre-submission phase") in accordance with guidance agreed by Member States[55]. Biocidal products containing active substances that meet the exclusion criteria and those of product-types 14, 15, 17, 20 and 21 are not eligible for Union authorisation.

The application for a Union authorisation must be submitted to ECHA. For the reference product applications following the assessment by an evaluating competent authority of a Member State, ECHA organises a peer review process resulting in an opinion by its BPC within 180 days. Companies can also apply for the Union authorisation of 'same biocidal products' as set out in Article 4 of Commission Implementing Regulation (EU) No 414/2013. Applications under this Regulation are linked to a related reference product, which can be an already authorised product or a product subject to an application for Union authorisation. ECHA prepares an opinion on the application for the same biocidal product within 30 days from the validation of the application by ECHA, or, where applicable, on the subsequent date of submission of an opinion on the related reference product. ECHA opinions represent the

[55] 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 .

basis for the Commission decisions on whether or not to grant the Union authorisation and under which conditions.

The timescale for initiating the Union authorisation varies, depending on whether the product contains a new or an existing active substance. Products containing new active substances, alone or in combination with existing active substances, have become eligible for Union authorisation from the entry into application of the BPR on 1 September 2013. For biocidal products containing existing active substances, the option of applying for Union authorisation has been made available in three stages, depending on the product-type (see Table 4.1).

Table 4.1: Timescales for the possibility to apply for Union authorisation

Product-types	*Union authorisation available from*
1, 3, 4, 5, 18, 19	1 September 2013
2, 6, 13	1 January 2017
7, 8, 9, 10, 11, 12, 16, 22	1 January 2020

Authorisations granted by Union authorisation are valid throughout the Union unless otherwise specified. However, in accordance with Article 44(5) of the BPR, a Member State can request the Commission to adjust certain conditions of the authorisation or that the Union authorisation shall not apply in the territory of that Member State. A Member State shall justify the request on the grounds included in Article 37(1) of the BPR (e.g. protection of health and life of humans or animals, protection of the environment, public security). No such request has been submitted to the Commission in the reporting period.

As required by Article 42(3) of the BPR, the Commission submitted a report[56] to the Council and European Parliament on the implementation of the provisions related to Union authorisation until 31 December 2017. The report provided an overview of the number and type of applications submitted until 31 December 2017 and included some preliminary conclusions based on the limited experience gained until that moment with the Union authorisation process. However, since no Union authorisation had been granted until that date, it was not possible to provide a comprehensive analysis of the functioning of the provisions related to Union authorisation.

Union authorisation of reference biocidal products

Figure 4.8 shows the number of Union authorisation applications submitted until 31 December 2019 and indicates the type of authorisation sought. Of the 138 applications submitted, 106 applications (77%) sought an authorisation for a biocidal product family and 32 (23%) sought an authorisation for a single biocidal product.

[56] Available at https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A0342%3AFIN.

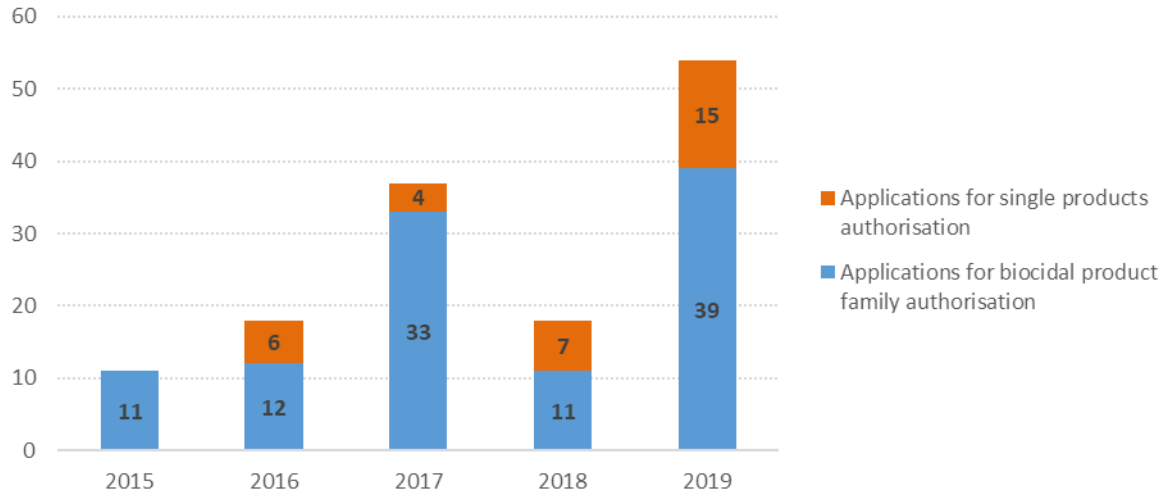


Figure 4.8: Number of applications for Union authorisation submitted per year and type of authorisation

The workload for the assessment of applications for Union authorisation were not evenly distributed among Member States (see Figure 4.9). 14 Member States accepted the role of evaluating competent authority for Union authorisation applications, with the Netherlands acting as evaluating competent authority for almost half of the applications. Article 43(1) of the BPR gives the applicant the right to freely choose the competent authority of the Member State that will evaluate the application. 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. Some Member States did not act as evaluating competent authority for any Union authorisation, as either they were not approached by applicants to hold this role, or they have not agreed to be the evaluating competent authority.

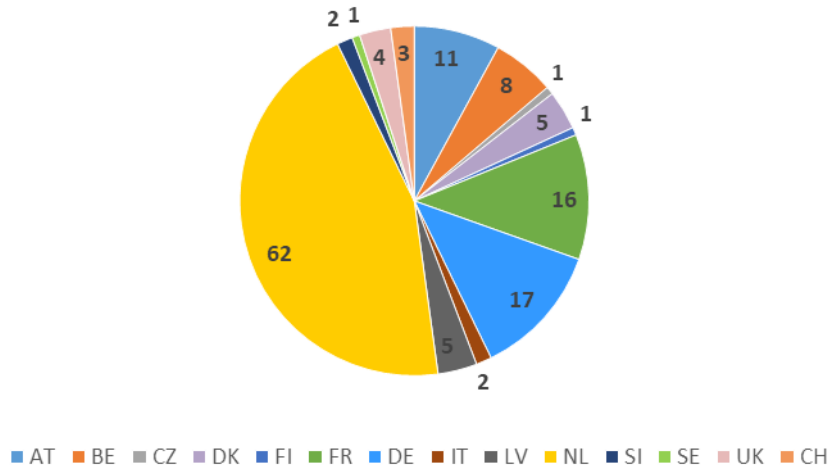


Figure 4.9: Distribution of Union authorisation by evaluating competent authority

The first Commission Implementing Regulations granting a Union authorisation were adopted in 2018. The Commission granted 11 Union authorisations in 2018 and 2019, of

which 10 concerned biocidal products families and 1 concerned a single biocidal product (see Figure 4.10).

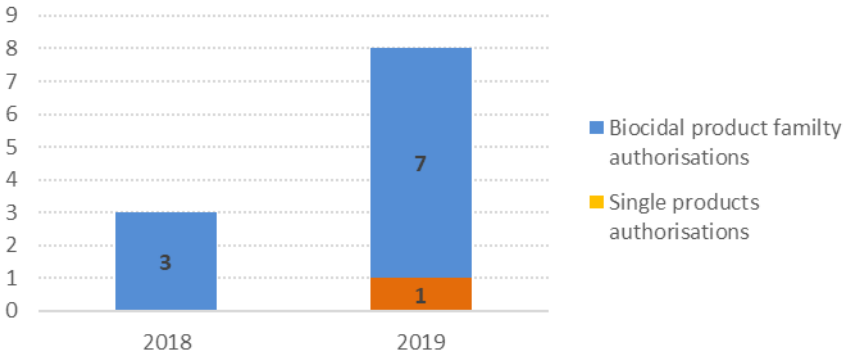


Figure 4.10: Number of Union authorisation authorisations by type of authorisation granted

Altogether the Union authorisations granted cover 67 biocidal products (see Figure 4.11). All products authorised are disinfectants and the great majority (63) are products for veterinary hygiene (product-type 3) and 4 of them are disinfectants not intended for direct application to humans or animals and disinfectants for food and feed area (product-types 2 and 4).

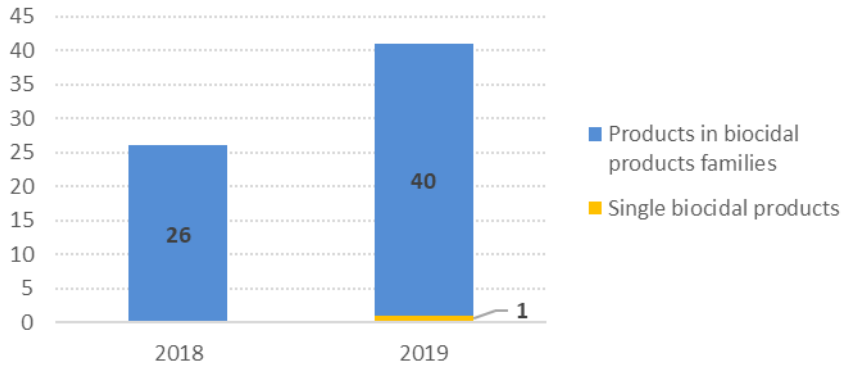


Figure 4.11 Number of products authorised by Union authorisation

As described in the earlier report from the Commission adopted in 2018, delays occur also in the Union authorisation procedures. Up to now it was not possible to complete the procedure for Union authorisation within the three years of the date of approval of the active substance, as specified in Article 89(3) of the BPR. The complexity of the dossiers, related in particular to the submission of extensive biocidal product families, additional information which needs to be submitted by the applicant, and the insufficient resources at competent authorities to address the number of applications, are the main reasons for the non-timely granting of the Union authorisations.

Union authorisation of same biocidal products

By 31 December 2019, 183 applications for Union authorisation of same biocidal products had been submitted, of which 78 concerned single biocidal products and 105 concerned biocidal products families (see Figure 4.12).

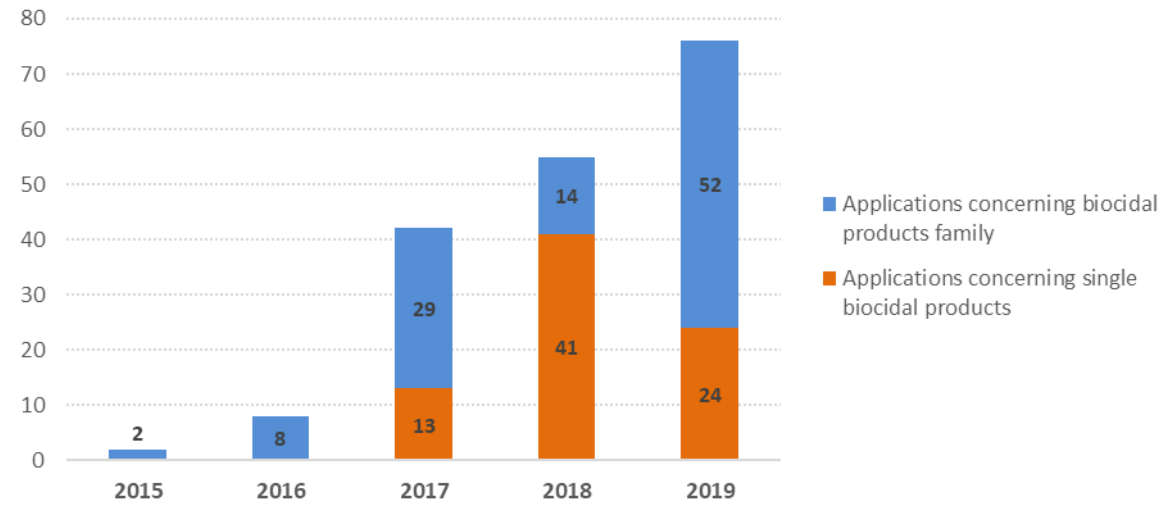


Figure 4.12: Number of applications for Union authorisation of same biocidal products

The Commission granted so far two Union authorisations for same biocidal products in 2018, since the evaluation of the related reference products for the other applications is still ongoing. They concern biocidal products families and cover 10 products used for veterinary hygiene (product-type 3).

4.4. Simplified authorisation

The simplified authorisation procedure established in Article 26 of the BPR aims to encourage the use of biocidal products which are less harmful for human and animal health and the environment. Biocidal products containing an active substance included in Annex I and which meet specific conditions (contain no substances of concern or nanomaterials, are sufficiently effective and their handling does not require the use of personal protective equipment) are eligible for the simplified authorisation procedure (Article 25 of the BPR).

The procedure for authorisation is similar to the procedure for national authorisation but the information requirements are much fewer and the deadline for completing the procedure is shorter (the competent authority evaluates the application and makes a decision on the authorisation in 90 days compared to 365 days for a national authorisation).

Products authorised in one Member State may be made available in other Member States without going through a mutual recognition procedure. A simple notification to the relevant Member State before actually placing the products on its market is sufficient (Article 27(1)).

So far, 239 biocidal products were authorised overall in Member States by simplified procedure, of which 36 are single biocidal products and 203 are members of biocidal products families. Almost 70% of these products contain lactic acid as an active substance product-types 1 to 4) and 20% of them contain tartaric acid and sodium benzoate as active substances, in product-types 1, 2 and 4. Figure 4.13 shows the number of products authorised by simplified authorisation per year in all Member States and figure 4.14 shows the number of products authorised by simplified authorisation by each Member States. 7 Member States granted simplified authorisations.

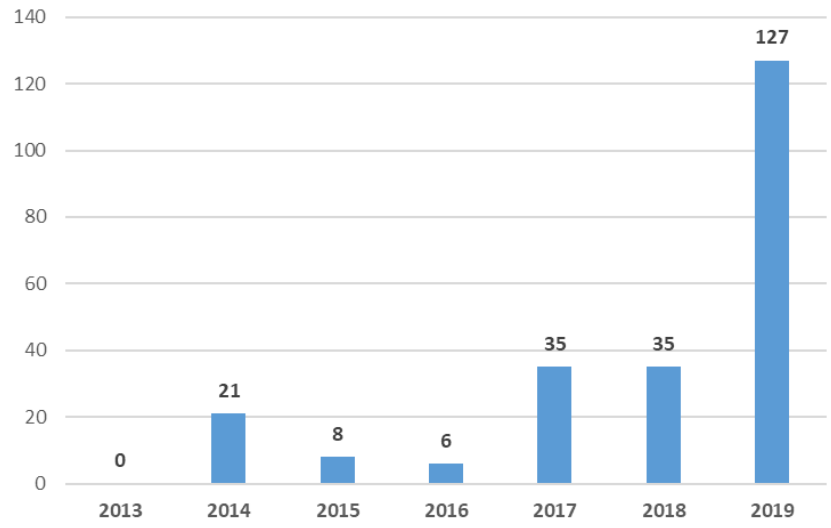


Figure 4.13: Overall number of products authorised by simplified authorisation per year

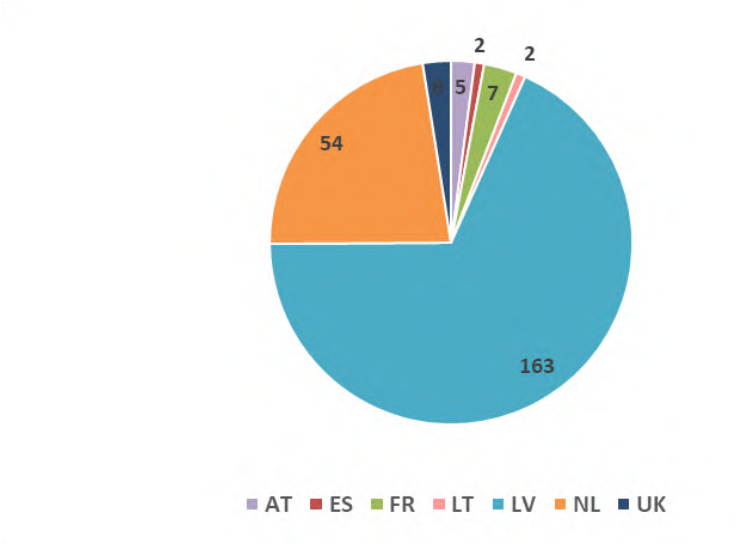


Figure 4.14: Number of products authorised by simplified authorisation in Member States

Biocidal products authorised via simplified authorisation may be made available on the market in all Member States, following a notification submitted by the authorisation holder to the respective Member States. Notifications of making available on the market were received by all Member States and their overall number is 474. Most notifications were submitted in France (52), followed by Germany (29) and Belgium (28). Figure 4.15 shows the number of notifications to Member States submitted in the reporting period.

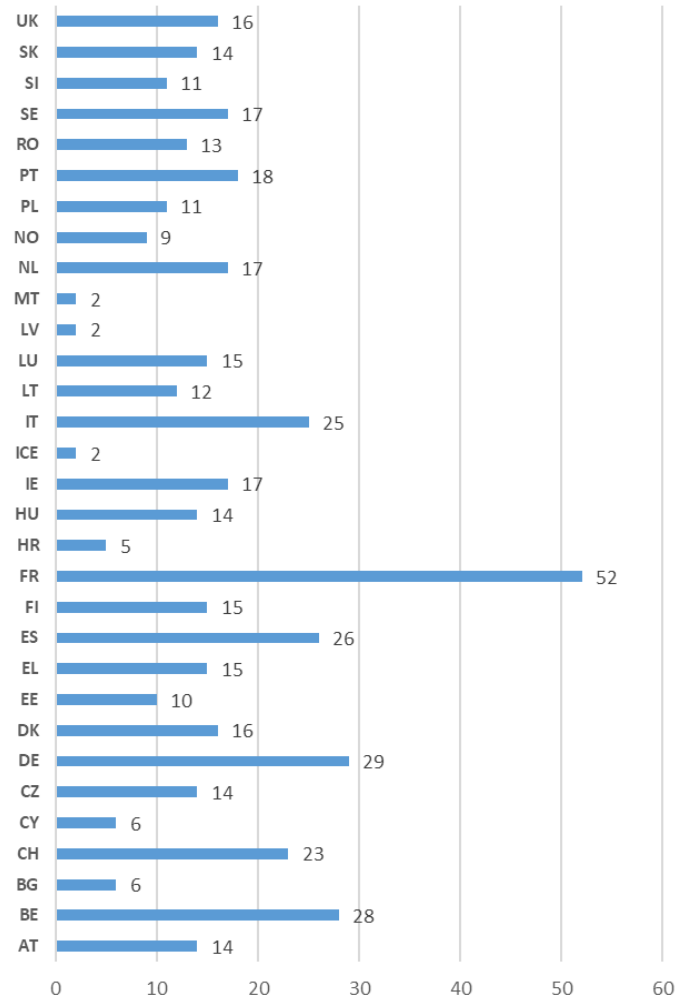


Figure 4.15: Number of notifications of making available on the market in the various Member States

4.5. Authorisation of products containing an active substance meeting exclusion criteria

Products containing an active substance which meets one or more of the exclusion criteria may be authorised only if there is negligible risks from the exposure to the substance, if the product is essential to prevent or control a serious danger to human health, animal health or the environment, or if not authorising the product would have a disproportionate negative effect for society when compared to the risks caused by the use of the product (Article 5(2) of the BPR). In all cases, the availability of suitable and sufficient alternative substances or alternative techniques should be a key consideration. In case a derogation possibility applies, the product authorisation is granted for a maximum period of five years.

Data on the number of applications for authorisation assessed according to Article 5(2) were provided by 21 Member States. These vary greatly, with 5 Member States having performed more than 100 such assessments (Germany, Ireland, Poland, Greece, United Kingdom) and one Member State (France) having performed more than 300.

In 14 Member States all the assessments resulted in authorisations. In the other Member States, the percentage of assessments resulting in non-authorisations varies between 3% and

20%. Figure 4.16 shows the number of assessments in each Member State and indicates how many of them resulted in non-authorisations.

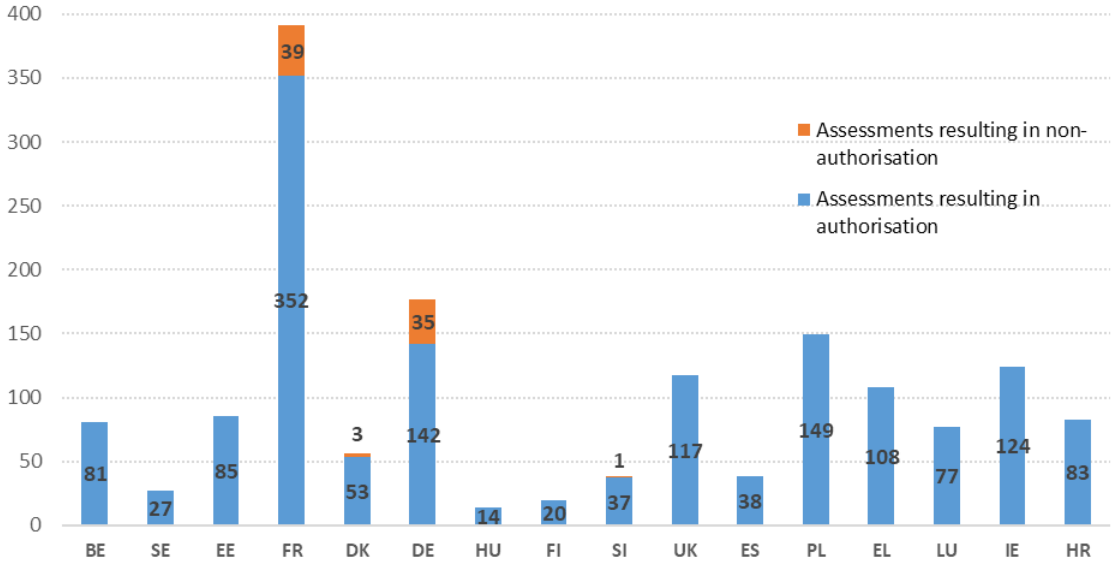


Figure 4.16: Number of Article 5(2) assessments resulting in authorisations and non-authorisations

4.6. Product authorisation renewal

Applications for renewal of authorisations of a biocidal product must be submitted at least 550 days before the expiry date of the authorisation, otherwise the product has to be removed from the market within 180 days after the expiry of the initial authorisation. So far the authorisations (granted by standalone national authorisation, mutual recognition or simplified authorisation) of 2,144 biocidal products were renewed. Figure 4.17 shows the number of products for which the authorisation was renewed in each Member State.

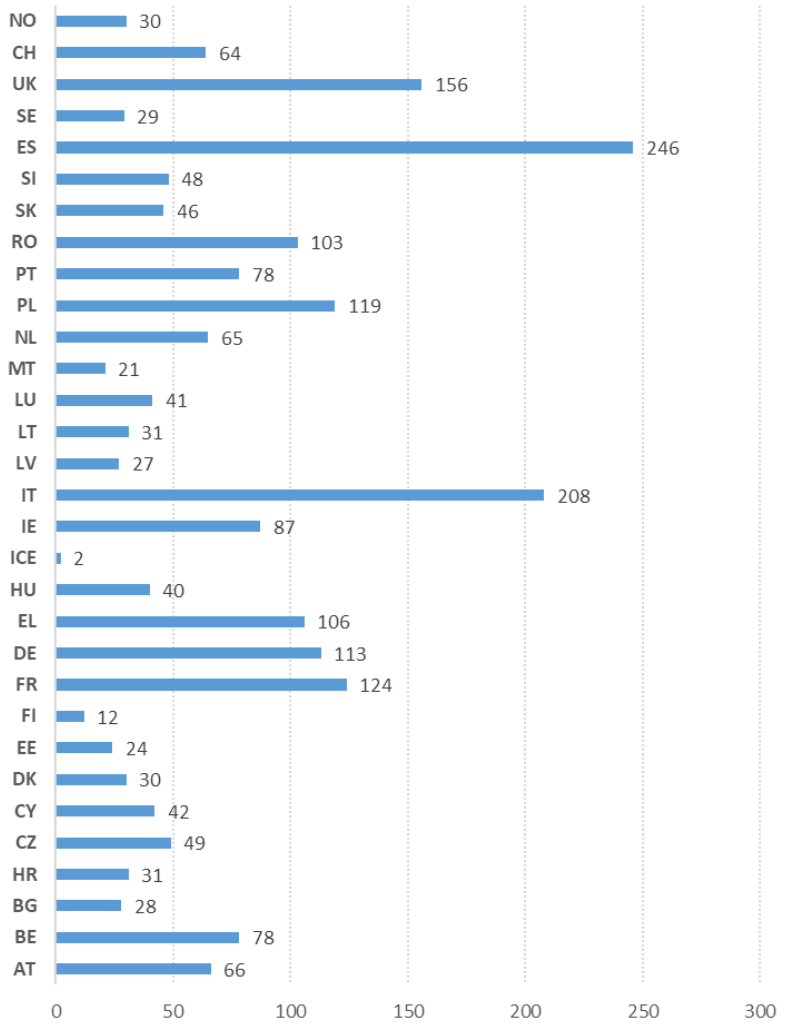


Figure 4.17: Number of renewals of product authorisations in each Member State

Figure 4.18 shows the overall number of products whose authorisation was renewed each year in all Member States.

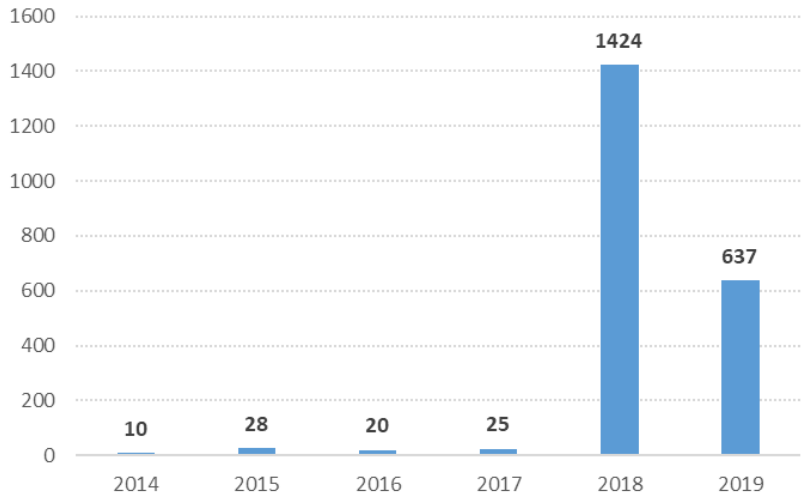


Figure 4.18: Number of renewals of product authorisations per year in all Member States

4.7. Authorisation granted on the basis of Article 19(5) of the BPR

According to the conditions laid down in Article 19(1)(iii) and (iv) of the BPR, biocidal products which have unacceptable effects on the health of humans or animals or on the environment cannot be authorised. Article 19(4)(c) establishes that biocidal products which contain a (active or non-active) substance having PBT/vPvB properties cannot be authorised for use by the general public. However, as provided in Article 19(5) of the BPR, by way of derogation from these provisions, products having unacceptable effects on human or animal health or on the environment can be authorised, and products containing a substance having PBT/vPvB properties can be authorised for use by the general public, when not authorising such products would have a disproportionate negative impact for society when compared to the risks for human health, animal health or the environment resulting from the use of the products. Appropriate risk mitigation measures must be set at the authorisation of such products, in order to minimise the exposure of humans and the environment to those products.

Altogether 14 Member States reported to have granted authorisations pursuant to Article 19(5). The number of authorisations varies greatly among Member States, with the higher number reported by France (356 authorisations), followed by the United Kingdom (211), the Netherlands (30) and Denmark (28) (Figure 4.19).

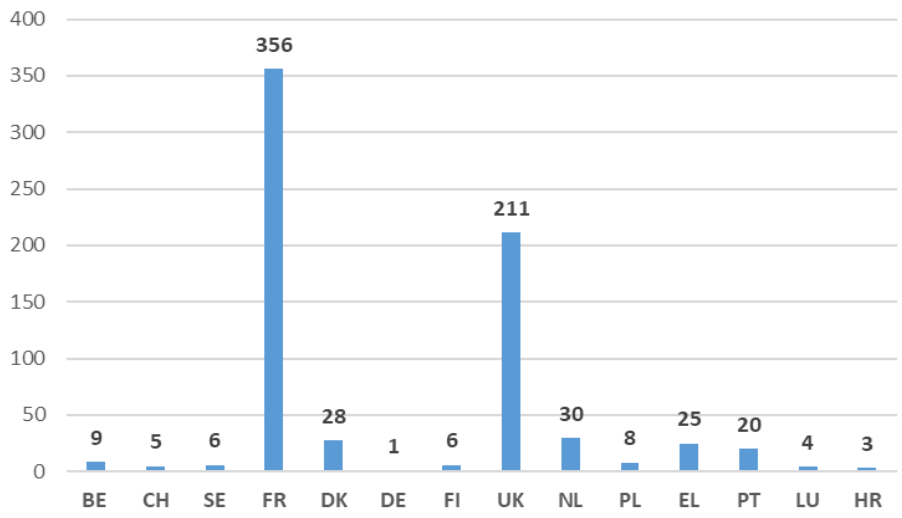


Figure 4.19: Number of authorisations granted pursuant to Article 19(5) of the BPR

Figure 4.20 illustrates the number of authorisations pursuant to Article 19(5) granted in the Union every year. Overall 712 such authorisations were granted, with the highest number recorded in 2014 (205).

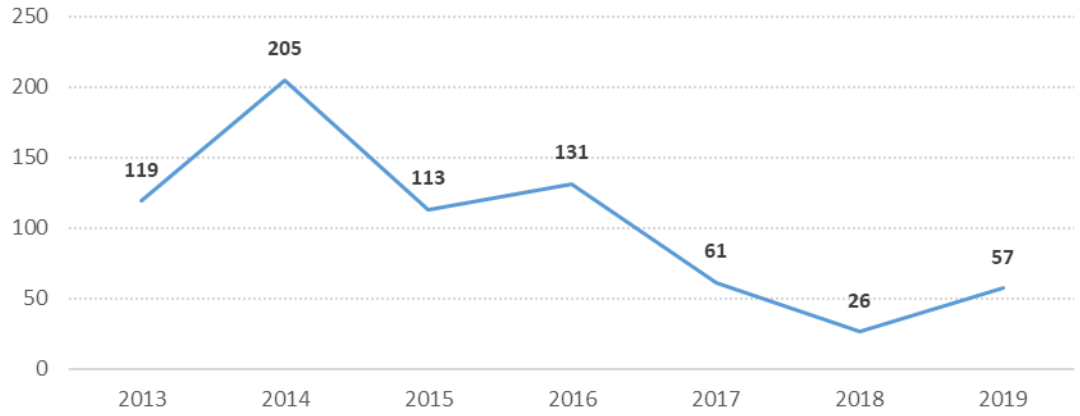


Figure 4.20: Number of authorisations granted according to Article 19(5)

4.8. Comparative assessment

If the application for authorisation concerns a product containing an active substance identified as candidate for substitution in accordance with Article 10(1) (see section 3 above), the evaluating competent authority must perform a comparative assessment as provided for by Article 23 of the BPR, in order to assess whether alternative authorised products or other methods are available for the use specified in the application which present a lower overall risk for human health, animal health and the environment, are sufficiently effective, present no other economic or practical disadvantages and provide sufficient chemical diversity to minimise the occurrence of resistance in the target harmful organism. The comparative assessment may lead to an authorisation without restrictions, an authorisation with restrictions or to the prohibition to make that product available on the market. If an authorisation (with or without restrictions) is granted, its maximum duration is 5 years. Member State may authorise such a product without conducting a comparative assessment in exceptional cases, where it is necessary to acquire experience first through using that product in practice, but only for four years.

The number of comparative assessments performed varies greatly among the 17 Member States who reported on this, with a maximum of 364 comparative assessments performed by France during the reporting period (see Figure 4.21). Most Member States indicated to have performed the highest number of assessments in 2014.

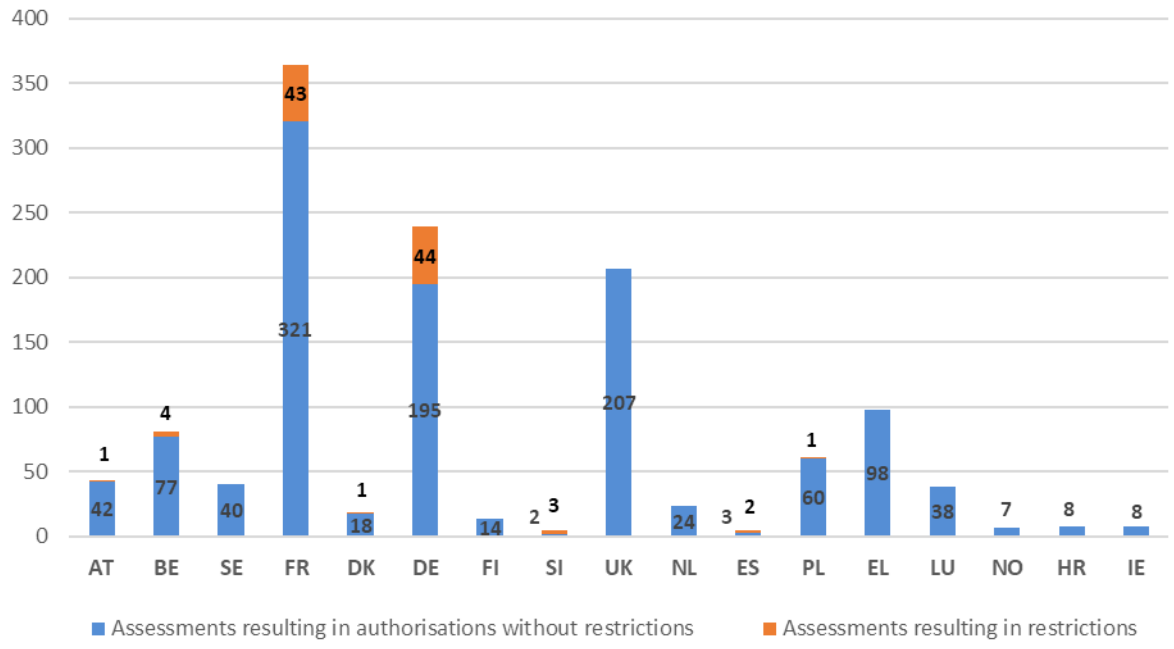


Figure 4.21: Number of comparative assessments performed in the 17 Member States that reported on this issue

The vast majority of the comparative assessment performed – and for several Member States all the assessments performed – led to an authorisation without restrictions. Overall the rate of comparative assessments resulting in restrictions or refusals varied between 0 (in 2013) and 16% (in 2019).

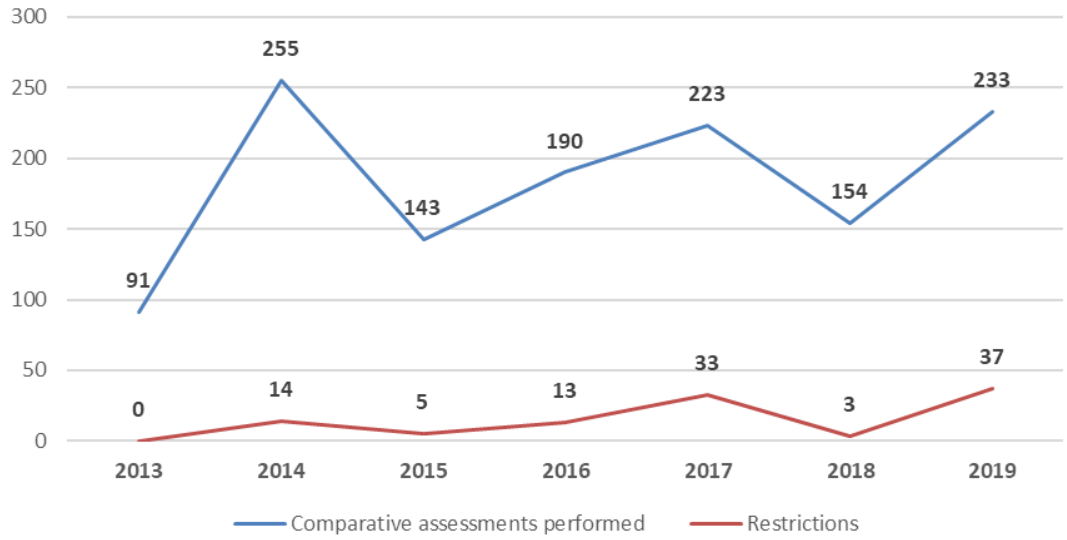


Figure 4.22: Overall number of comparative assessments performed and number of restrictions

A notable example of products for the authorisation of which a comparative assessments has to be performed are anticoagulant rodenticides (Art. 14), since all approved active substances for use in such products are candidates for substitution. In addition to assessing whether the

derogation possibilities in Article 5(2) are met, as these active substances meets also the exclusion criteria, Member States must also perform a comparative assessment.

Specific questions arising during the comparative assessment can be referred by Member States to the Commission. According to Article 23(5) of the BPR, where the comparative assessment involves a question which, by reason of its scale or consequences, would be better addressed at Union level, in particular where it is relevant to two or more competent authorities, the competent authority may refer the question to the Commission for a decision In 2015, in the context of the comparative assessment to be carried out at the renewal of anticoagulant rodenticide products, five questions were referred to the Commission. A Commission Implementing Decision[57] addressing those questions was adopted in 2017, based on an opinion delivered by the BPC[58] upon request of the Commission.

4.9. Derogations from the requirements for authorisation

Article 55 of the BPR foresees several instances in which biocidal products can be made available on the market without authorisation.

(i) Permission for limited and controlled use in the event of danger to human health, animal health and the environment, which cannot be contained by other means

According to Article 55 (1) of the BPR, Member States can permit the making available on the market and use of non-authorised biocidal products for a period not exceeding 180 days (often referred to as emergency permits).

In the period 2014 to 2019, 9 Member States granted a total of 135 permits for limited and controlled use. 57 permits were issued for product-type 3 products used in apiaries. Emergency permits have also been issued for insecticides (product-type 18); rodenticides (product-type 14) repellents for the control of pine processionary caterpillars (product-type 19) and products for the control of other vertebrates (product-type 20) (see Figure 4.23).

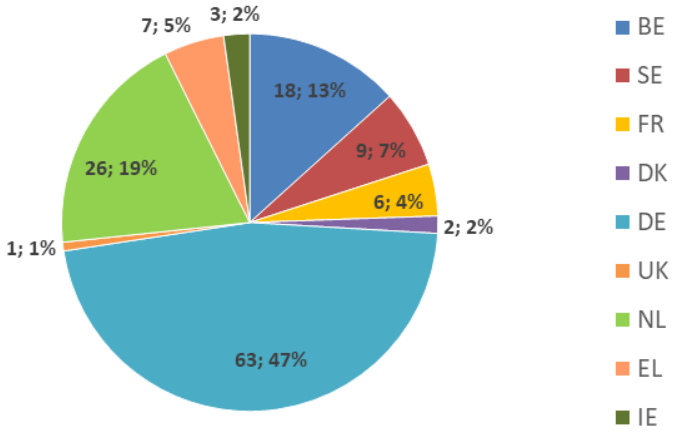


Figure 4.23: Permits granted by Member States in accordance with Article 55(1)

[57] Commission Implementing Decision (EU) 2017/1532. OJ L 232, 8.9.2017, p. 11–16)

[58] https://echa.europa.eu/documents/10162/24209689/bpc_opinion_comparative-assessment_ar_en.pdf/bf81f0a5-3e95-6b7d-d601-37db9bb16fa5

When granting such permits Member States are required to inform the other Member States and the Commission of the permits and of the justification for issuing them. The Commission publishes the notifications received and keeps an updated overview[59] of all notifications.

These temporary permits may be extended by a Member States for a maximum of 550 days following a reasoned request from that Member State to the Commission and adoption of a Commission Decision after a vote in the Standing Committee for Biocidal Products allowing the Member State to extend the original permit. The Commission had to decide on six requests for extension and in all cases it allowed an extension of the permits for the maximum period envisaged. Five of the six Commission Decisions allowing an extension concerned insecticides[60] and one concerned a biocidal product for the control of other vertebrates[61]. In five of these cases, the requesting Member States were either evaluating the application for regular product authorisation or were seeking ways to authorise the product on their territory by mutual recognition of the product already authorised in another Member State. In one case, the active substance contained in the biocidal product was still under evaluation by the same Member State requesting the extension.

(ii) Provisional authorisation for a biocidal product containing a new active substance, which is not yet approved.

In accordance with Article 55(2) of the BPR, provisional authorisation may be granted for a maximum of three years (and renewed for one year) if a competent authority that evaluated an application for the approval of the active substance has submitted a recommendation to ECHA for approval, and the Member State receiving the application for provisional authorisation (or ECHA for Union authorisation) considers that the biocidal product is expected to comply with the conditions for authorisation laid down in Article 19.

So far, only France granted one provisional authorisation pursuant to Article 55(2) in 2013, for a biocidal product containing *Bacillus thuringiensis* subsp. *kurstaki*, strain ABTS-351 used for the control of oak processionary caterpillars. The provisional authorisation was renewed for one year in 2016. Following the completion of the peer review by the BPC, the Commission adopted a decision to approve the active substance at the end of 2016.

(iii) Authorisation for the protection of cultural heritage

In accordance with Article 55(3), Member States may, upon derogation granted by the Commission, authorise biocidal products containing a non-approved active substance if it is proven that the active substance is essential for the protection of cultural heritage and no appropriate alternatives are available. In order to obtain such derogation, Member States have to apply to the Commission and provide due justification.

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[59] Available at https://circabc.europa.eu/w/browse/92bd0162-f4b3-49a7-9351-76cf1037287a

[60] Three decisions concerned products containing *Bacillus thuringiensis* subsp. *israelensis* for the control of larvae and adult invasive mosquitoes (in two cases) and midges (in one case); one concerned a product containing *Bacillus thuringiensis* subsp. *israelensis* and *Bacillus sphaericus* for the control of larvae of exotic mosquites; one concerned a product containing (*Z*)-13-hexadecen-11-yn-1-yl acetate for the control of pine processionary caterpillars.

[61] The decision concerned a product containing aluminium phosphide releasing phosphine for the control of rabbits on the site of the Zaventem airport.

During the reporting period, no authorisation was granted by Member States pursuant to Article 55(3). However, in 2019, Austria and Spain applied to the Commission requesting a derogation allowing them to authorise products consisting of *in-situ* generated nitrogen for the protection of cultural heritage[62], given that many museums and cultural institutions have been using nitrogen generated *in-situ* in specific treatment chambers to control harmful organisms on cultural heritage objects.

Currently, nitrogen is included in Annex I to the BPR with the restriction that it is only allowed for use in limited quantities in ready-for-use canisters. Nitrogen is also approved for use in biocidal products in product-type 18 (insecticides). However, nitrogen generated *in situ* is not approved, not included in Annex I, and not included in the Review Programme. Following the submission of the applications by Austria and Spain, discussions took place between the Commission, Member States and two international organisations representing museums and cultural heritage institutions (International Council of Museums - ICOM[63] and International Council on Monuments and Sites - ICOMOS[64]). The two organisations representing museums and cultural heritage sites undertook to pursue a long-term solution and indicated their intention to submit an application for inclusion of nitrogen generated *in-situ* into Annex I to the BPR, which is expected to be submitted in 2021. In the meantime, following the two applications submitted in 2019, the Commission has adopted Decisions[65] allowing Austria and Spain to authorise products consisting of in-situ nitrogen for the protection of cultural heritage.

4.10. Research and development

To encourage research and development in relation to active substances and biocidal products, Article 56 of the BPR allows experiments or tests involving non-authorised biocidal products and non-approved active substances intended exclusively for use in biocidal products, under certain conditions.

Experiments or tests that may involve or result in the release of the biocidal product in the environment must be notified in advance to the competent authority of the Member State where the experiment or test will take place. The competent authority may decide to prohibit or restrict them, where they could have harmful effects on the health of humans or animals or unacceptable effects on the environment.

The highest number of such notifications was submitted in the Netherlands (overall 96 in the reported period), followed by the UK (90 notifications) and Spain (50 notifications) (see Figure 4.24). In the Member States having received more than 10 notifications in the reporting period, approximately 80% of the experiments notified were allowed, and 20% were prohibited.

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[62] In 2020, other six Member States (Denmark, France, Germany, the Netherlands, Poland and Portugal) requested similar derogation pursuant to Article 55(3) and Decisions following five of them were adopted (Implementing Decisions (EU) 2020/1047, 2020/1049, 2020/1265, 2020/1266 and 2020/1755).

[63] https://icom.museum/en/

[64] https://www.icomos.org/en

[65] Implementing Decisions (EU) 2020/1040 and 2020/1050.

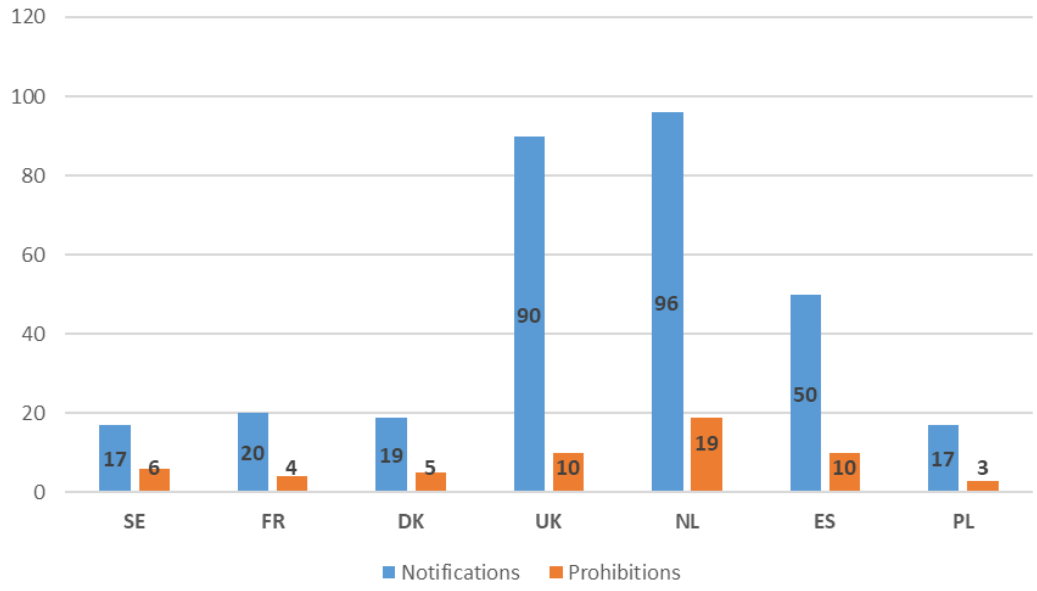

Figure 4.24: Number of test/experiment notifications and number of prohibitions in 7 Member States

4.11. Notification of unexpected or adverse effects

As set out in Article 47 of the BPR, the holder of an authorisation has the obligation to notify the competent authority having granted a national authorisation and ECHA (or the Commission and ECHA in case of Union authorisation) if he becomes aware of new information, that may affect the authorisation, on adverse effects of the biocidal product or of the active substance contained therein, of data regarding the potential of the active substance for the development of resistance and of new information indicating that the product is not sufficiently effective. Based on the information provided by the authorisation holder, the competent authority (or the Agency, in case of Union authorisations) may decide to amend or cancel the authorisation.

No notification of unexpected or adverse effects were submitted so far.

4.12. Parallel trade permits

For the purpose of facilitating the movement of biocidal products in the Union, Article 53 of the BPR provides for the granting of parallel trade permits. Parallel trade permit allows, upon request from the applicant, the making available on the market of a Member State (Member State of introduction) of a product authorised in another Member State (Member State of origin), if it is deemed by the competent authority of the Member State of introduction that the product is identical[66] to a biocidal product already authorised in the Member State of introduction.

During the reporting period, 18 applications for parallel trade permits were submitted and 14 permits were granted (see Figure 4.25). Member States having granted parallel trade permits are Belgium (2), Cyprus (7), Ireland (3) and the Netherlands (2).

[66] The product is manufactured by the same company or in accordance with the same manufacturing process, contains the same active substances and has essentially identical composition.

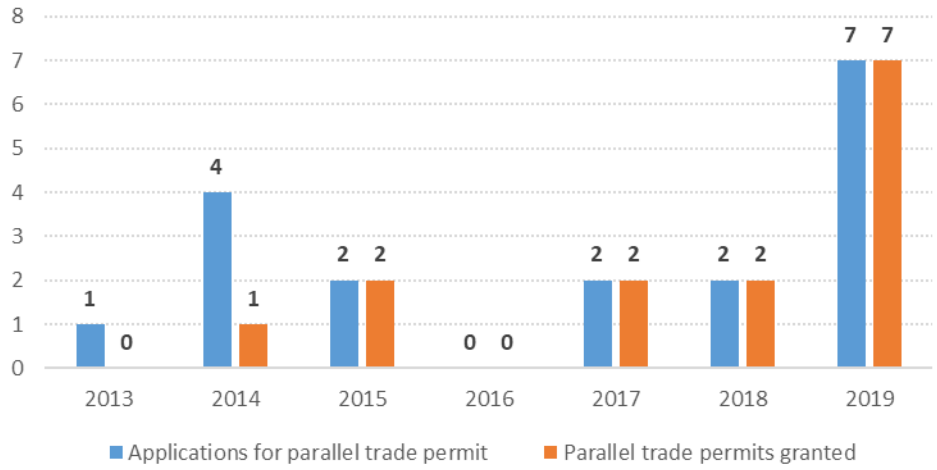

Figure 4.25: Number of applications for parallel trade permits and permits granted per year

4.13. Products made available on the market under the transitional measures

As foreseen in Article 89(3) of the BPR, biocidal products containing active substance(s) included in the Review Programme (see section 3.1) can be made available on the market and used subject to national laws of Member States, pending the final decision on the approval or non-approval of the active substance(s).

All Member States except for Iceland and Austria have informed about national measures or legislation for the making available on the market of biocidal products during the transitional period. The situation in Member States is very diverse. In some cases the national system is a notification system (i.e. companies must submit a notification and the notification has to be accepted by the competent authority before products may be made available on the market). Several Member States (e.g. Belgium, France, Latvia, Slovenia, Spain) keep a national database/register/inventory[67] of products made available on their market. In some cases (e.g. Spain) such database does not include all product-types and is limited to specific ones. The Netherlands requires that an authorisation is granted - following national assessment procedures - before products may be made available on the market. In some Member States (e.g. Belgium, Denmark, Norway, Spain, Sweden) biocidal products of certain product-types or for specific uses within a product-type need to be authorised following a limited or full scientific assessment of the properties of the products.

Not all Member States were able to provide data regarding the number of products made available on the market under a national regime. Where submitted, data were in some cases incomplete and did not include all product-types. Member States reported the data related to products made available on the market under the transitional measures differently - some reported the number of products newly made available on the market each year, some referred to the total number of products available on the market each year and some other ones only reported the number products whose making available on the market required, under their system, an authorisation. Consequently data cannot be aggregated at Union level.

[67] The French national database is available at https://simmbad.fr/public/servlet/accueilGrandPublic.html
For Belgium https://www.health.belgium.be/en/list-authorised-biocides-and-annual-report#1

However, it can be concluded from the data available that the number of products made available under the transitional measures is, globally, in the order of several tens of thousands. It appears that most of these products are disinfection products, followed by pest control products and preservatives.

These data and the data reported in section 4.3 and 4.4. (national authorisation and mutual recognition) indicate that, in line with the limited progress of the Review Programme as reported in section 3.1, the majority of biocidal products currently present on the market in the Member States is still made available under national transitional rules and without having undergone a full assessment in line with the criteria set out in the BPR.

5. TREATED ARTICLES

Treated articles are defined as any substance, mixture or article which intentionally incorporates or has been treated with one or more biocidal products (Article 3(1)(l)). The BPR regulates the placing on the market of treated articles (the first making available on the market) and according to its provisions all articles placed on the Union market can only be treated with biocidal products containing approved active substances or, according to the transitional measures, included in the Review Programme.

A wide range of everyday products are treated with biocidal products – mainly for the purpose of preservation: paints, furniture, sport articles, kitchen utensils, textile products, flooring products, etc.

To enable consumers to make informed choices and to facilitate enforcement, the BPR established specific labelling requirements for treated articles (Article 58). When a claim is made regarding the biocidal properties of the article or when the conditions set at the approval of the active substance require so, manufacturers, importers or others who place the treated articles on the market are required to label them. The label must contain specific elements, among which the statement that the article incorporates one or more biocidal products and the name of the active substance contained in the product(s). At the same time, companies manufacturing or supplying treated articles must be ready to provide consumers free of charge with information about the biocidal treatment of the article they are selling if the consumer so requests.

Seven Member States reported information on controls performed between 2013 and 2018. The controls on the legal presence of the active substance in treated articles revealed that relatively few articles were treated with non-allowed active substance. The percentage of non-compliances varied between 0 % (Switzerland) and 28% (Lithuania). Germany reported the highest number of controls performed (1112) and identified approximately 10% of non-compliant cases. On the other hand, controls on the completeness and correctness of the label of treated articles found that overall at least 30% of the articles controlled had an incorrect or incomplete labelling and in some Member States this percentage was particularly high, for instance 78% in Belgium and 83% in Sweden, and 60 % in Switzerland.

Some Member States organised specific campaigns and surveys intended to monitor and assess the situation on their market with regard to treated articles (e.g., market survey on articles treated with biocides run by the Swedish Chemicals Agency[68] and market monitoring of façade coatings containing biocidal products run by the Swiss Federal Office for Public Health[69]). The market survey run by the Swedish Chemicals Agency in 2016 showed that numerous treated articles were present on the market, mainly treated with biocidal products in the following product-types: product-type 2 (disinfectants and algaecides not intended for

[68] The study is available at https://www.kemi.se/download/18.60cca3b41708a8aecdbb6a8c/1586793296149/pm-6-16-market-survey-on-articles-treated-with-biocides.pdf

[69] The project report is available at https://www.anmeldestelle.admin.ch/dam/chem/en/dokumente/download-listen/chemikalien-kampagnen/bericht-kampagne-biozide-in-fassaden-2016-2017.pdf.download.pdf/report-biocidal-products-in-facade-coatings-campaign-2016-2017.pdf

application to humans or animals), product-type 3 (veterinary hygiene), product-type 4 (food and feed area), product-type 6 (preservatives for products during storage), product-type 7 (film preservatives), product-type 9 (fibre, leather, rubber and polymerised preservatives), product-type 10 (construction material preservatives), product-type 18 (insecticides) and product-type 19 (repellents and attractants). The majority of the articles considered for the survey failed to comply with the labelling requirements and only in few cases the name of the active substance was indicated. The survey showed that many actors on the market, especially suppliers of treated articles, were not aware of the requirements under the BPR.

BEF-1 enforcement project

Following the information collected by 7 Member States between 2013 and 2018, a coordinated programme of controls with regard to treated articles was carried out in 2019 in the context of the first harmonised enforcement project run by the BPR Subgroup of the Forum[70]. The main objectives of the project, in which 22 Member States participated, were to check compliance - with regard to the legality of the active substance in the treated article and to the correctness and completeness of labelling - and to assess the awareness and competence among the actors on the market concerning the BPR requirements for treated articles.

More than 1800 treated articles were checked, of which 70% were articles and 30% were mixtures[71]. The most controlled categories of treated articles were clothing and bedding (for articles) and paints and chemical mixtures (for mixtures). The majority of inspections (84%) were carried out on-site, while 10% were desktop inspections (conducted from the office) and 10% were performed as web survey. The majority of the companies inspected were making available treated articles on the market and in 16% of the cases companies had a dual role, both placing and making available treated articles on the market. Most controlled companies were micro-sized enterprises, followed by small- and medium-sized companies.

The most frequent product-types identified for the biocidal product used for the treatment or incorporation were product-type 2 and product-type 9 for articles and product-type 6 and product-type 7 for mixtures. The majority of the treated articles checked (73%) were manufactured within the European Union, 11% were imported and 16% were of unknown origin.

- Findings on the legality of the presence of active substance(s) in treated articles

  One of the central elements in the BPR - that only allowed active substances (either approved or in the Review Programme or for which an application for approval has been submitted before 1st September 2016) may be used to treat articles - seemed to be very well fulfilled. Less than 2.5% of the treated articles checked contained an illegal active substance.

[70] The Forum for Exchange of Information on Enforcement (Forum) is an ECHA body which coordinates a network of authorities responsible for the enforcement of chemicals regulations in the EU. The BPR Subgroup of the Forum focuses on coordinated and harmonised enforcement of the BPR (https://echa.europa.eu/about-us/who-we-are/enforcement-forum).

[71] The definition of treated article in Article 3(1)(l) of the BPR covers both, articles and mixtures as defined in the REACH Regulation.

The ten most frequent active substances present in articles and in mixtures, respectively, are indicated in Tables 5.1 and 5.2 below.

Table 5.1: Ten most common active substances identified in articles

Active substance identified in articles	% of articles containing the active substance
Pyrithione zinc	9
Reaction mass of titanium dioxide and silver chloride	6
Permethrin	5
Tosylchloramide sodium (Chloramin T)	5
Geraniol	4
Silver phosphate glass	4
1,2-benzisothiazol-3(2H)-one (BIT)	4
Alkyl (C12-16) dimethylbenzyl ammonium chloride / (ADBAC/BKC C12-C16)	4
Silver	4
Copper(II) carbonate-copper(II) hydroxide (1:1)	3

Table 5.2 Ten most common active substances identified in mixtures

Active substances found in mixtures	% of the mixtures containing the active substance
1,2-benzisothiazol-3(2H)-one (BIT)	31
Mixture of 5-chloro-2-methyl-2H-isothiazol-3-one (EINECS 247-500-7) and 2-methyl-2H-isothiazol-3-one (EINECS 220-239-6) (CMIT/MIT)	22
2-methyl-2H-isothiazol-3-one (MIT)	22
3-iodo-2-propynylbutylcarbamate (IPBC)	17
2-Octyl-2H-isothiazol-3-one (OIT)	14
4,5-dichloro-2-octyl-2H-isothiazol-3-one (DCOIT)	12
Pyrithione zinc	6
Bronopol	3
Terbutryn	2
5-Chloro-2-methyl-2H-isothiazol-3-one (CIT)	2

The most frequent non-allowed active substances found in articles were silver chloride (2% of the articles checked) and silver (1%), while in mixtures these were 1,2-benzisothiazol-3(2H)-one (BIT) and bronopol. In most cases they were used in a different product type than the one(s) allowed, therefore their specific use was incompliant with the requirements of the BPR.

- Findings on labelling requirements

The compliance rate was high (90%) as to the presence of the label when required, with almost 100% compliance rate for mixtures. However, when considering the quality and completeness of the information to be provided on the label, only 58% of the articles and 77% of the mixtures were compliant. The most common deficiencies in labelling were the lack of indication of the name of the active substance and the statement that the article incorporates/was treated with a biocidal product. The requirement for labels in the national language seems to be well met, but there was great variation between Member States. For Member States with dual official languages this type of incompliance was high.

The identified non-compliances led to various enforcement measures. The most frequent measure was written advice (in 45% of the cases), followed by verbal advice (17% of the cases), administrative orders (8%) and fines (4%).

With regard to the consumers' right to information as set out in Article 58(5), it appears that it is either not very well known by consumers or, if known, consumer interest seems to be low, as less than 20% of the companies indicated to have received a consumer request about a treated article. However, when requests were submitted by consumers, over 75% of the companies answered the questions in due time.

The project report[72] identified a need for industry and competent authorities of Member States to take measures to raise awareness and increase knowledge among companies about responsibilities and legal requirements in relation to treated articles. The report also concluded that efforts should be made by companies to improve the quality of the labels.

[72] Available at https://echa.europa.eu/documents/10162/13555/bef_1_report_en.pdf/8e0e4520-3c41-92d2-0e9f-199109ee8f5f

6. POISONING INCIDENTS

All Member States have appointed poison centres or bodies that offer the services of a poison centre, where incidents related to the use of biocides involving human or animals are reported. Poison centres in different Member States use different scales to record the severity of the incidents and some of them do not differentiate between incidents involving biocides and plant protection products. Therefore, a full aggregation and comparison of data to cover all Member States is not possible. Some Member States were not able to provide data for every year of the reporting period, especially for the very first years. Latvia, in addition to the incidents reported to the poison centre, also included in the reporting the number of cases of persons admitted to the emergency services of hospitals due to suspected poisonings with biocidal products.

Some Member States differentiated between fatal and near fatal incidents (i.e. incidents leading to death or severe health impairments) and incidents with other severity level.

Figure 6.1 provides a summary of the data provided by 19 Member States[73], where data were available for most of the reporting years and could be aggregated. The highest number of poisoning incidents involved disinfectants (between 47% and 59% of the incidents recorded yearly) and pest control products (between 39 and 50%), followed by preservatives (approximately 2% of the reported incidents) and other biocidal products (less than 1% of the cases.

For the incidents with disinfection products the information available indicates that a great part of the of cases involved product-type 2 disinfectants (for instance chlorine-based products and products containing quaternary ammonium compounds). They concerned adults and the main route of exposure was inhalation, due to either improper use, mostly by mixing the products with strong acids during cleaning operations, or due to the instability of the solid forms (in the case of chlorine-based products, for instance pool disinfecting products in granules or tablets). For poisonings with pest control products, the information available shows that rodenticides and products to combat ants, crawling insects and flies were the most often involved, followed by insect repellents. The incidents mainly concerned children and animals/pets and the exposure route was mainly oral (ingestion of baits). When incidents concerned pets ingesting rodenticide baits, they were fatal in most of the cases.

Some Member States consider rodenticides to be among the most problematic biocidal products that are available to the general public. In Sweden, a strong increase in poisoning incidents of cats through rodenticides containing alphachloralose was reported in 2019. This led the competent authority to amend the authorisation of products containing this active substance in accordance with Article 48 of the BPR, restricting the use to trained professional users only.

[73] Austria, Belgium, Sweden, Estonia, Denmark, Romania, Germany, Lithuania, Hungary, Slovakia, United Kingdom, Netherlands, Spain, Latvia, Poland, Luxembourg, Norway, Malta, Ireland

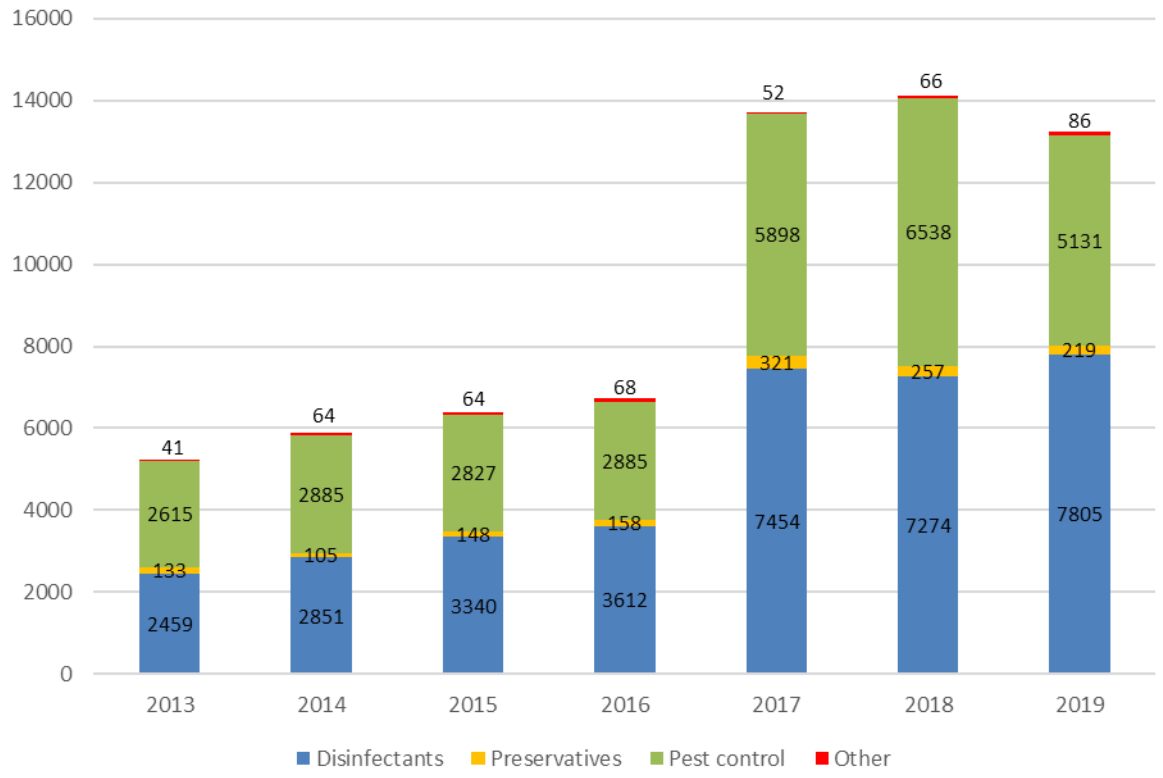

Figure 6.1: Number of poisoning incidents by main group of products

The number of poisoning incidents reported to the poison centres shows an increase from 2016 to 2017, followed by a stable trend. The increase from 2016 and 2017 may be explained by the increased quantities of biocides made available on the market (as reported for instance by Belgium) and increased use by population (therefore an increased exposure), but also by an increased visibility of poison centres among the general public.

Figure 6.2 illustrates the evolution per year of the total number of poisoning incidents reported by the 19 Member States, which were able to provide such data, by main group of product-types.

Overall, the vast majority of exposures were accidental and a minority of the cases were due to intentional or occupational exposure. Only one Member State (Latvia) reported data regarding occupational diseases related to biocides. 24 cases were registered in Latvia between 2015 and 2017, they mostly involved disinfectants and the professionals concerned were generally healthcare professionals (e.g. nurses, anaesthesiologists).

As to the severity of the poisonings, the highest number of fatal or near fatal incidents involved pest control products. Between 50 and 95 such cases per year were registered overall (in the 19 Member States having provided detailed data). For incidents involving disinfectants, the number of fatal or near fatal incidents ranged between 5 and 76 per year, while for the ones involving preservatives and other biocidal products the number ranged between 3 and 13 and 2 and 5, respectively. However, when considered in proportion to the total of cases reported for the respective main group of biocidal products, the incidents involving disinfectants were very severe (fatal or near fatal) in 0.1 to 1% of the cases; in 2 to

7% of the cases for preservatives, 1 to 3% of the cases for pest control products and in 3 to 10% of the cases for other biocidal products.

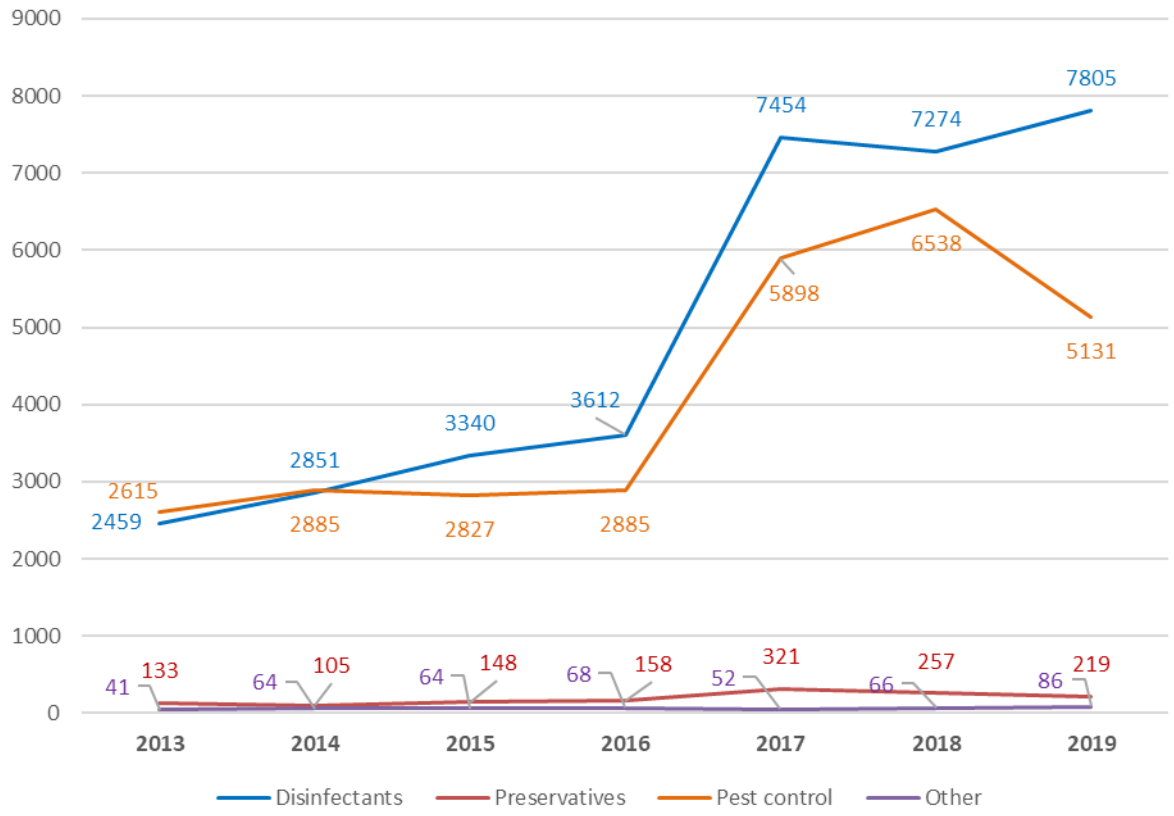

Figure 6.2 Overall number of poisoning incidents by year in 19 Member States

Some Member States carried out specific investigations with regard to poisoning incidents in their territories. In France several studies were performed on the exposure to and incidents related to the use of various biocidal products (e.g. accidental exposure to chlorinated cleaning products for swimming pools and spas, exposure to products containing phosphides related to the transport or handling of shipping containers, skin and eye reactions to insect repellent bracelets[74]).

The study on accidental exposure to chlorinated cleaning products for swimming pools and spas[75] analysed 1494 cases recorded by poison centres in France between January 2010 and June 2019. A marked seasonality was observed, with a maximum number of cases recorded in the third quarter of each year. Almost all cases occurred in the general public, with a very small proportion concerning work-related exposure (96,6% vs. 3,4%). Adults were involved in 60,4% of the cases, while in the case of children, - who accounted for 38,6% of the cases – very young children (of less than 5 years of age) were involved in 21,7% of the cases. Overall, inhalation was the most common route of exposure and it concerned the majority of adults involved, while for very young children most frequently exposure occurred by oral

[74] Study report available at https://www.anses.fr/fr/system/files/Toxicovigilance2012SA0277Ra.pdf

[75] Study report available at https://www.anses.fr/fr/system/files/Toxicovigilance2019SA0192Ra.pdf

route. Of the cases analysed, 10 were severe[76] and 9 of these concerned adults. The study concludes that the majority of cases in adults could have been avoided by compliance with precautionary measures (concerning for instance the opening of packaging, mixing with other products) and highlights a clear lack of awareness of the risks associated with the handling of chlorinated products, despite the instructions for use and the warnings on the packaging. As a follow-up of this study, the French competent authority published in July 2019 a news item on its website, recalling the instructions for preservation, handling and compliance with doses of these products. In the presence of humidity, phosphides release phosphine, which may cause irritant or corrosive effects or even cause severe systemic poisoning, depending on the concentration.

The French study on exposure products containing phosphides during unloading and opening of containers[77] analysed incident reported to the poison centres between 1999 and 2007. Phosphide containing products are used as insecticides or rodenticides and are used, among others, to treat storage places such as containers, by fumigation. 12 exposure cases were analysed, all occurring in professional context and concerning males with an average age of 35,7 years. The most frequently involved route of exposure was respiratory, sometimes associated with dermal or eye exposure. All cases of symptomatic exposure were subject to medical consultation, mostly in an emergency service (9 cases). The study shows that occupational exposure to phosphide or phosphine release, although poorly documented, has been a reality in recent years for staff working in contact with containers. The report also makes reference to a 2018 report[78] of the European Agency for Safety and Health at Work (EU-OSHA), which mentions the presence of phosphine in a significant percentage of containers in European ports report and notices the lack of proper labelling and security rules. The French study report recommended authorities to strengthen the monitoring of labelling and also recommended regular awareness-raisings for people handling containers, as well as systematic detection of residues of fumigant gases when containers are opened.

In Germany the Federal Institute for Risk Assessment in co-operation with the eight poison centres carried out a pilot study[79] as part of a research project on all pesticides in relation to which enquiries to the poison centres were made between May 2018 and 2019. The study reported around 2 600 cases involving plant protection products or biocides, of which around 300 concerned exposure to repellents. The study showed that the most common exposure route in children was the oral route (more than 50%), while inhalation was the predominant exposure route for the elderly and adults (around 45%), followed by oral and dermal exposure. In 2 cases moderate symptoms were reported, while none of the cases was life-threatening. The study also showed that products whose authorisation expired or that were banned already for some time are still privately owned and involved in poisoning incidents (e.g. parathion, banned in the Union since 2001).

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[76] The gravity of the cases was differentiated between low, moderate and severe.

[77] Study report available at https://www.anses.fr/fr/system/files/Toxicovigilance2018SA0290Ra.pdf

[78] https://osha.europa.eu/en/publications/handling-fumigated-containers-ports-health-risks-and-prevention-practices-0/view

[79] Study report available at https://www.bmu.de/themen/forschung-foerderung/forschung/forschungs-und-entwicklungsberichte/details/pilotstudie-zur-etablierung-eines-nationalen-vergiftungsmonitorings-im-verbund-mit-der-gesellschaft/

7. SUSTAINABLE USE

Measures to achieve a more sustainable use of biocidal products have the objective of reducing the risks and impacts of the use of biocidal products on human health, animal health and the environment and of promoting the use of integrated pest management and of alternative approaches or techniques, where feasible, such as non-chemical alternatives to biocidal products. At present, the Directive on the Sustainable Use of Pesticides does not apply to biocidal products[80] and options for extending its scope to cover biocidal products are not being considered during the impact assessment for the revision of this Directive[81]. The usefulness of such an extension will be considered in the context of a future evaluation of the BPR.

In March 2016, as required by the provisions of Article 18 of the BPR, the Commission submitted to the Council and the European Parliament a report[82] on how the BPR contributes to the sustainable use of biocidal products. The report highlighted that the procedures under the BPR for substance approval, product authorisation and comparative assessment of biocidal products containing candidates for substitution (with the aim of phasing-out their use) were already important contributions to the objective of fostering the sustainable use of biocidal products. The main priorities identified by the report for promoting the sustainable use of biocidal products were therefore the completion of the ongoing assessment of all existing active substances (the Review Programme) and the subsequent timely authorisation of products containing them according to the BPR rules.

This finding remains still valid and crucial, especially considering the slow progress in the past years towards the completion of the Review Programme and the significant delays in both the active substance approval and product authorisation processes.

As a follow-up of the report, Member States were requested to provide information on four elements stemming from the report: availability of best practice documents, availability of certification or training schemes for professional users, information to the public on risks and benefits associated with the use of biocidal products and measures taken to address the risk from the use of biocidal products in specific settings (such as schools, work places, public spaces). In the majority of Member States actions were taken under at least one of these four elements, while this was not the case in four Member States (Greece, Luxembourg, Cyprus and Italy).

In 13 Member States best practices documents were developed in order to reduce the use of biocidal products or to use biocides with less impact on human health and the environment. These are available in the form of guidance documents, brochures or standards and most often concern best practices related to the use of pest control products (product-types 14, 18, 19, 20)[83]. The majority of these documents concern the safe use of rodenticides and methods

[80] See recital 2 of Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (OJ L 309, 24.11.2009, p. 71–86).

[81] https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides_en

[82] Available at: https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:52016DC0151

[83] Some examples: in Denmark https://www2.mst.dk/Udgiv /publikationer/2019/05/978- 87-7038-075-1.pdf , https://mst.dk/media/94459 /vejledning-tilautorisationsbekg_ 2016_04 07.pdf, in Ireland https://www.pcs.agriculture.gov.ie/media/pesticides/content/biocides/Permanent%20Baiting%20Rules.pdf,

for the control of rodents in professional settings (farms, food and feed production). Some best practices documents regard the use of disinfection products and alternatives to traditional anti-fouling products. In Belgium a general document covering biocides was developed, as well as a yearly brochure on the use of pesticides (including biocides) at home and in the garden.

Certification or training schemes for professional users are present in 20 Member States and under development in two others. In all Member States where such schemes exist, training or certification is compulsory for operators providing professional pest control services using insecticides and rodenticides. Rodent control and proper training to operators is given high consideration in all Member States. In Finland a specific qualification for the use by farmers of rodenticides restricted to trained professionals is foreseen. Special attention is also given in some Member States (e.g. Germany and Switzerland) to the use of insecticides by fumigation. In eight Member States such schemes cover professional disinfection services, in particular the use of product-type 2 products (mainly for swimming pool disinfection) and product-type 5 products (drinking water disinfection). Specific certification schemes for the professional application of wood preservatives (product-type 8) are foreseen in six Member States (Estonia, France, Germany, Netherlands, Finland, Sweden), Liechtenstein and Switzerland. Specific authorisations are needed in several Member States for the use of gaseous pest control products of product-type 20. In the Netherlands, even though no training scheme is in place, a specific network (Biocides knowledge network[84]) is set up to increase and exchange knowledge about biocides.

The provisions of Article 17(5) of the BPR require Member States to take necessary measures to provide the public with appropriate information on benefits and risks associated to the use of biocidal products and on ways of minimising their use. 21 Member States reported to have taken measures to convey such information to the public. In most cases this is done by means of information published on the website of competent authorities on specific biocides-related topics and on appropriate handling of and alternatives to biocidal products. For instance, in Sweden information is available on antifouling paints[85], wood protection[86] and pest control[87]; in Denmark information is available on modalities to prevent and remove algae without using biocides[88], modalities to remove and prevent insects in kitchens[89]; in Germany information on the use of biocides (including best practice, storage, disposal and non-biocidal methods of control)[90]is available.

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https://www.pcs.agriculture.gov.ie/media/pesticides/content/biocides/EffectiveControlRodentPestsFarms300916.pdf, the Netherlands https://kpmb.nl/KPMB/media/KPMB/Documenten/IPM%20Rattenbeheersing/20160222-KPMB-Handboek-beheersing-rattenpopulaties-buiten-gebouwen-Versie-2-0.pdf

84 https://www.kennisnetwerkbiociden.nl/

85 https://www.kemi.se/kemikalier-i-vardagen/rad-om-kemikalier-som-du-har-hemma/batbottenfarger

86 https://www.kemi.se/download/18.6df1d3df171c243fb237665a/1590504275284/faktablad-information-om-impregnerat-virke.pdf

87 https://www.kemi.se/privatpersoner/rad-om-kemikalier-som-du-har-hemma/medel-mot-skadedjur-och-insekter

88 https://mst.dk/kemi/biocider/borger-og-biocider/alger-paa-fliser-og-terrasser/

89 https://mst.dk/kemi/biocider/borger-og-biocider/insekter-i-koekkenet/

90 https://www.umweltbundesamt.de/themen/chemikalien/biozide

Some Member States have organised information campaigns on specific topics. For instance, in Finland such campaigns related to treated articles[91] (in 2015-2016), insecticides and repellents[92] (in 2017-2018) and antifouling products[93] (2015 to 2019). In Belgium a yearly event is organised ("Week without pesticides"), where updated brochures and folders are distributed to the public and information campaigns are organised also at regional level in order to minimise the use of biocides by the general public[94]. In Lithuania public awareness campaigns on the safe and sustainable use of biocides are organised every year, with information published on internet websites, interviews in local and national press, television and radio. In Latvia informative lectures are given yearly by the competent authority in universities; seasonal information campaigns on the use of specific biocides (for instance rodenticides, insecticides) are published in the media.

Sixteen Member States reported to have taken measures to address the risk related to the use of biocides in specific areas such as schools, kindergartens, workplaces and public spaces. Many of these were information campaigns on the safe use of rodenticides and on permanent baiting in public spaces and others were specifically targeted to children. In Finland, in 2014 information[95] was published on the use of biocides in public places. In Slovenia, leaflets with information on the excessive use of repellents and on classification and labelling of chemicals were distributed in schools.

91 https://tukes.fi/-/tarkeaa-tietoa-biosideilla-kasitellyista-tuotteista, https://tukes.fi/-/ala-osta-myrkyllisia-sahkopylvai-1

92 https://tukes.fi/-/valta-turhaa-biosidien-kayttoa-hyonteisten-torjunnassa, https://tukes.fi/-/osta-vain-suomessa-hyvaksyttyja-hyonteiskarkotteita-ja-lue-kayttoohjeet-huolel-1

93 https://tukes.fi/-/veneilykausi-alkaa-saasta-ymparistoa-ja-valta-antifoulingvalmisteiden-kaytt-1, https://tukes.fi/-/vastuullinen-veneilija-ei-kayta-myrkkymaaleja, https://tukes.fi/documents/5470659/11781251/Antifouling-esite/0c8ab6a0-6d13-df8b-0381-723573598d18/Antifouling-esite.pdf

94 https://www.vmm.be/mijn-gifvrije-tuin

95 https://tukes.fi/-/tietoa-ja-harkintaa-tarvitaan-kaytettaessa-desinfiointiaineita-julkisissa-tilois-1

8. ENFORCEMENT

Enforcement of the BPR, as for other pieces of EU chemicals legislation, is a national responsibility. An effective enforcement of the BPR in Member States is crucial for achieving its objectives. As set out in Article 65(2) of the BPR, each Member State is required to ensure that an appropriate system of official controls is in place in order to enforce compliance with the BPR. Administrative structures differ between Member States and often more than one authority plays a role in the enforcement of the BPR. In 13 Member States (e.g. Finland, Sweden, France, Slovenia) one authority is responsible for the BPR enforcement while in eight Member States the enforcement responsibility is shared between multiple authorities. In some Member States (e.g. Austria, Germany, Spain) enforcement is carried out by authorities at regional level; co-operation and co-ordination between these regional authorities is foreseen in order to ensure a harmonised enforcement in the respective Member States.

Enforcement strategies

A well designed enforcement strategy should allow enforcement to be effective, achieving the best possible outcome in terms of compliance, while keeping costs low. According to the reports provided by Member States, an overall strategy for BPR enforcement has been implemented in 20 Member States. In most cases it comprises both proactive (risk-based) controls and reactive interventions, following complaints or as follow-up controls. The proactive controls may be in the form of controls in the context of annual control plans or special enforcement campaigns (e.g. controls of specific groups of products), periodic controls of authorisation holders or random check of products or distributors.

Complaints

In many cases controls follow complaints concerning alleged infringements of the BPR. Data with regard to complaints were available in 23 Member States and indicate that in 11 Member States more than 100 complaints were received over the reporting period. The highest number of complaints was recorded in Romania (1284), followed by Germany (823), Denmark (758), the Netherlands (716) and Poland (639). It was not reported how many of these complaints lead to inspections and sanctions. Figure 8.1 shows the evolution of the overall number of complaints in the reporting Member States.

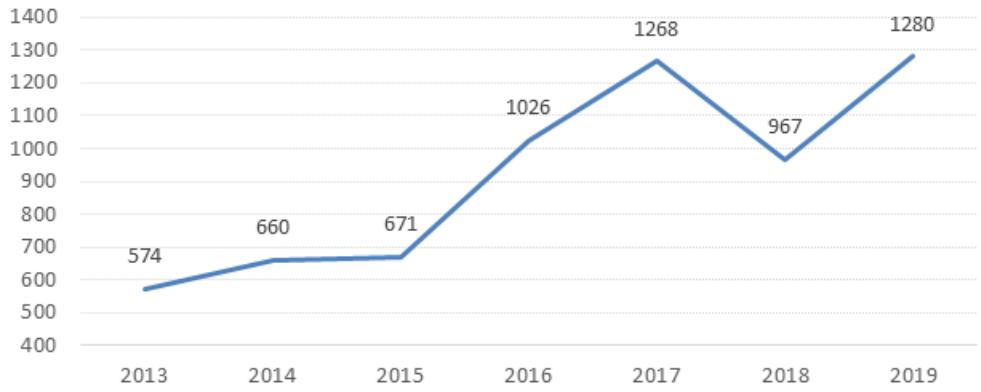

Figure 8.1: Overall number of complaints per year in the reporting 23 Member States

Official controls

Member States were requested to submit data related to controls on compliance with BPR rules for making available biocidal products on the market, controls on biocidal products made available under the transitional rules, controls on manufacturers, controls on end-users, controls on residues and controls on treated articles. The information reported with regard to controls of treated articles is included in section 5 above. Substantial differences exist in the number and type of controls carried out by Member States.

Not all Member States were able to provide actual figures of controls and non-compliances and where they did, in some cases, data was not available per year or for every year of the reporting period. Therefore the reported data on controls by Member States does not allow the aggregation of data at Union level.

- *Controls on compliance with the BPR rules for making products available on the market*

The controls reported cover biocidal products made available on the market, records kept by authorisation holders, classification, labelling and packaging of biocidal products, safety data sheets, and advertising.

The results of the controls on biocidal products vary greatly between Member States. The reported non compliances refer to products containing an active substance not approved or not approved for the specific product-type of the product, products subject to BPR authorisation but not authorised, and products made available not in accordance with the conditions in the authorisation.

In Austria the overall non-compliance rate during the reporting period was 12% for disinfectants, 10% for preservatives, 11% for pest control products and 18% for other biocidal products. Relatively low non-compliance rates were also reported by Lithuania (between 3 and 7% non-compliance rate) and Hungary[96] (around 6% non-compliances). On the other hand, France reported higher non-compliance findings: more than 27% for disinfectants, preservatives and pest control products and higher than 20% for other products, with peaks of around 40% non-compliances registered in 2017 and 2018. High non-compliance rates were also reported by Latvia (between 15% and 55% during the reporting period), Luxembourg (with an average of 58% non-compliances), Estonia (between 27% and 61%) and Denmark (more than 80% non-compliances). The high rate of non-compliance reported by some Member States might be related to the fact that most controls performed were reactive controls, i.e. following complaints of suspected non-compliant products on the market.

Controls on classification, labelling and packaging of biocidal products (as laid down in Article 69 of the BPR) indicated overall non-compliance rates (for all product-types during the reporting period) of 11% in Austria, 8% in Belgium, 20% in France, 6% in Hungary, 35% in Estonia and 1% in Lithuania.

High compliance was generally registered in Member States with regard to the requirement of inclusion of active substance suppliers in the official list referred to in Article 95 of the BPR.

[96] Data was available only for controls performed in 2018 and 2019.

- *Controls on biocidal products made available on the market under the transitional measures*

Again, different situations were reported by Member States. With regard to the controls of the active substances contained in products[97], in some Member States the level of compliance was high or very high (for instance in Belgium, France, Latvia, Hungary the non-compliance rate was less than 8%), while in others compliance was lower (for instance in Denmark and Germany)

Compliance of these products with national legislation was lower in all Member States. The non-compliance rate was 18% in Belgium and Latvia, 12% in France, up to 37% in Estonia, 65% in Luxembourg and more than 80% in Denmark.

- *Controls on manufacturers*

Controls regarding the availability of appropriate documentation in relation to the manufacturing process (as required by Article 65(2)) indicate high compliance in some Member States (e.g. Hungary, Austria), while in other Member States the level of compliance seems low (e.g. in Estonia, where the average non-compliance rate was 52% and almost all controls from 2016 to 2019 resulted in non-compliances).

- *Controls on end-users*

Controls on end-users check whether biocidal products are used according to the terms and conditions in their authorisation. In some Member States these controls concerned mainly the use of disinfection products in health care settings, farms or food-processing sectors and revealed low non-compliance rates (an average of 2.5% in Lithuania and 5% in Estonia, between 0.3 and 3% in Belgium). Higher non-compliance rates were reported by the Netherlands for controls in poultry farms (76% non-compliance in 2017), and tattoo/piercing shops (73% in 2017, 44% in 2018) and by Denmark with regard to controls on the use of pest control products (between 90% and 100% non-compliances during the reporting period). The controls in Denmark were re-active controls, due to complaints, and concerned the illegal possession and use of rodenticides which, according to their authorisation, were to be possessed and used only by authorised and trained professionals.

- *Controls on residues of active substances in food and feed*

Only four Member States (Estonia, Poland, Slovakia and Sweden) reported data on controls on the presence of residues of active substances in food and feed. In most cases, however, it was not possible to attribute the residues to a specific use (from plant protection use, from biocidal use, or from other uses).

Data provided indicates that in very few cases the residues in food and feed were higher than the EU harmonised maximum residue limit set in Regulation (EC) No 396/2005: on average 0.3% of the controls in Estonia, 0.8% in Sweden, 1.2% in Poland and 9% in Slovakia revealed residues higher than the maximum residue limit.

[97] Active substances contained in such products must be included in the Review Programme.

Harmonisation of enforcement

The BPR Subgroup of the Forum for the exchange of information on enforcement (BPRS)[98], which started its operation in 2017, contributes to the harmonisation of enforcement at EU level. Practical issues encountered by inspectors during enforcement are discussed in this forum and common solutions and conclusions are identified, allowing inspectors in Member States to approach in the same (harmonised) manner future similar cases.

The BPRS also designs and manages harmonised enforcement projects, which entail that the same type of control is carried out in all participating Member States at the same time, following the same procedure. The first harmonised enforcement project, on treated articles, had its operational phase in 2019 (see section 5 above for further information). The second project, focusing on active substances in biocidal products, is under preparation and is scheduled to have its operational phase in 2022.

[98] https://echa.europa.eu/about-us/who-we-are/enforcement-forum

9. USE OF NANOMATERIALS IN BIOCIDAL PRODUCTS

The BPR was the first piece of legislation that incorporates the definition of nanomaterials[99] as laid down in the Commission Recommendation of 18 October 2011[100]. Nanomaterials are materials which often have specific properties due to their small particle size. In the light of current knowledge, nanomaterials are similar to normal chemical substances, in that some may be toxic and some may not. Possible risks are related to specific nanomaterials and specific uses. Therefore, nanomaterials require a risk assessment which should be performed on a case-by-case basis, using pertinent information.

Specific rules for nanomaterials are included in the BPR. For instance, according to Article 4(4) of the BPR, the approval of an active substance does not cover nanomaterials, except where explicitly mentioned. When nanomaterials are present in a biocidal product, the risk to human health, animal health and the environment has to be assessed separately (Article 19(1)(f)) and biocidal products containing nanomaterials are not eligible for simplified authorisation (Article 25(c)). If biocidal products containing nanomaterials are used to treat an article, the label of the treated article - when required according to Article 58(3) - has to indicate the name of all nanomaterials contained in the biocidal product, followed by the word 'nano' in brackets.

So far, two active substances which are nanomaterials have been approved: pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide and synthetic amorphous silicon dioxide (nano), both for use in insecticide products. One product containing the approved active substance synthetic amorphous silicon dioxide (nano) was authorised in 11 Member States[101]. For this product, due to aggregation/agglomeration in the final product, it was concluded that no exposure to the nanoscale primary particles is expected during its use, therefore no particular safety measures in relation to the presence of nanomaterial needed to be put in place for the use of the product.

Two other active substances were still under assessment within the review programme: silver as a nanomaterial[102] and silver adsorbed on silicon dioxide as a nanomaterial in the form of a stable aggregate with primary particles in the nanoscale.

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[99] Nanomaterial means a natural or manufactures active (or non-active) substance containing particles, in an unbound state or as an aggregate or as an agglomerate and where, for 50% or more of the particles in the number size distribution, one or more external dimensions is in the size range 1-100 nm. Fullerenes, graphene flakes and single-wall carbon nanotubes with one or more external dimensions below 1nm are considered as nanomaterials.

[100] Commission Recommendation of 18 October 2011 on the definition of nanomaterial (OJ L 275, 20.10.2011, p. 38–40).

[101] https://echa.europa.eu/information-on-chemicals/biocidal-products/-/disbp/factsheet/FR-0013670-0000/authorisationid

[102] In 2020 the related application for approval was rejected due to applicant's failure to pay the fees.

10. THE ROLE OF BIOCIDAL PRODUCTS IN THE COVID-19 PANDEMIC

Although the COVID-19 pandemic started in 2020, hence outside the period covered by this Staff Working Document, the particular importance of biocidal products in this context and the actions taken by the Commission, Member States, and industry should be mentioned.

In fact, good hygiene practices are a key preventative measure against the spread of pathogens such as SARS-CoV-2. Apart from washing hands with soap and water, the use of alcohol-based hand disinfectants was recommended by the World Health Organisation as a means to control the spread of the virus.

Already during the first weeks of the pandemic in February/March 2020, severe shortages in the supply of disinfectants of product-type 1 (mainly hand disinfectants) and product-type 2 (surface disinfectants) became apparent, following a steep increase in demand. The Commission engaged immediately in dialogue with both Member States and industry associations representing suppliers of active substances and disinfectant products. Periodic surveys (weekly or bi-monthly) provided by relevant industry associations to the Commission allowed to monitor the market situation for disinfectants and understand the challenges faced by companies. Major challenges identified were related to the availability of some active substances and co-formulants for mixture formulations of disinfectants, limited production capacities, lack of personnel at factory level, sourcing of primary packaging for these products and supply chain disruptions due to uncoordinated border closures.

To address the shortages of disinfectants, and to prevent the occurrence of future shortages, it was necessary to speed up the supply by making full use of all possible provisions of the BPR. As described in section 4.9 Article 55(1) allows Member States to grant emergency permits for products that, although containing an approved active substance, do not have an authorisation under the BPR on grounds of, among others, danger to public health. Such products contain for example propan-1-ol, propan-2-ol, active chlorine generated from sodium hypochlorite or hydrogen peroxide. For products containing active substances still under evaluation in the Review Programme (notably ethanol), Member States can apply suitable provisions under national legislation (in accordance with Article 89(3) of the BPR) for possible emergency derogations.

In addition to numerous exchanges by mail, the Commission organised an ad-hoc meeting of competent authorities and ECHA on 26 March 2020 to discuss and clarify all possibilities to increase the supply in disinfectants and published[103] information and guidance documents for Member States. It also encouraged[104] Member States to refrain from establishing unilateral national restrictions to the free movement of essential supplies like disinfection products, which create significant barriers and negatively affected Member States' capacity to contain the COVID-19 pandemic. The Commission also provided input to the document on surface disinfectants[105] developed by the European Centre for Disease Prevention and Control.

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[103] https://circabc.europa.eu/w/browse/b47e31f5-0a5a-493b-813e-198b73c1efff.

[104] Commission communication on a coordinated economic response to the COVID-19 Outbreak, https://ec.europa.eu/info/sites/info/files/communication-coordinated-economic-response-covid19-march-2020_en.pdf.

[105] https://www.ecdc.europa.eu/sites/default/files/documents/Environmental-persistence-of-SARS_CoV_2-virus-Options-for-cleaning2020-03-26_0.pdf.

ECHA also launched dedicated webpages[106] with information for industry and national authorities. Industry associations developed a practical guide[107] aiming to assist companies in complying with their obligations under the BPR or under national laws during the COVID-19 pandemic.

In order to use new sources of approved active substances (for instance propan-1-ol or propan-2-ol), manufacturers need to submit a request for technical equivalence assessment of the new source. To accelerate the process ECHA put in place a fast track procedure for technical equivalence applications for propan-1-ol and propan-2-ol[108]. ECHA also issued recommendations on the compositional requirements for these two active substances[109], and for the active substances active chlorine released from sodium hypochlorite, hydrogen peroxide and peracetic acid[110].

As a result of this activities, 26 Member States made use of the possibility to grant temporary permits for disinfectants in accordance with Article 55(1). Some Member States (for example France, Estonia, the Netherlands) issued generic derogations for products formulated in accordance with WHO recommended formulations, while others (for instance Belgium, Slovakia, Italy) granted permits for individual products. More than 500 notifications[111] of permits granted by Member States were received by the Commission until November 2020. The permits were addressed either at specific companies or at broader categories of operators, like pharmacies or chemical companies and covered mainly products of product-type 1 (hand disinfectants) and 2 (surface disinfectants), both for professional and general public use. 12 Member States also granted permits for product-type 4 products (disinfectants for food and feed area). Among Member States that issued permits for individual products, Italy granted the highest number of permits (around 250), followed by Belgium (84) and Slovakia (44).

Eight months after the outbreak of the pandemic it can be concluded that the provisions in place under the current regulatory system to react to emergency situations have allowed to address the unprecedented situation during the Covid-19 pandemic. Thanks to the concerted efforts of industry, Member States and the Commission, new suppliers of biocidal active substances and disinfectants entered the market and existing suppliers expanded their production capacity to meet the hugely increased demand in disinfectants. Several companies donated substantial quantities of alcohol to the healthcare sector to make up for the shortages

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[106] https://echa.europa.eu/covid-19.

[107] https://specialty-chemicals.eu/ebpf-covid-19-practical-guide/.

[108] https://echa.europa.eu/documents/10162/28801697/accelerated_te_propanol_isopropanol_en.pdf/fe8d0741-3271-2938-1da8-f0e06b2aba8d.

[109] "Recommended requirements for the active substances Propan-1-ol and Propan-2-ol, for the purpose of derogations under Article 55(1) of the BPR", 23 March 2020, available at https://echa.europa.eu/documents/10162/28801697/recommended_requirements_propanol_isopropanol_en.pdf/ff333754-ea2f-f81c-ca96-874e59802806.

[110] "Recommended requirements for the active substances active chlorine released from sodium hypochlorite, hydrogen peroxide and peracetic acid", 7 April 2020, available at https://echa.europa.eu/documents/10162/28801697/recommended_requirements_propanol_isopropanol_en.pdf/ff333754-ea2f-f81c-ca96-874e59802806.

[111] The notifications are published at https://circabc.europa.eu/w/browse/47c6e2b3-27a1-4137-83e4-9605a64e2de7. An overview of all notifications is available at https://circabc.europa.eu/w/browse/92bd0162-f4b3-49a7-9351-76cf1037287a.

registered. However, the high demand of disinfectants appeared to attract some new suppliers that took advantage of the situation, as authorities reported cases of disinfectants that do not have the required authorisation or permit, or lack the proper labelling[112].

The feedback received from Member States and economic operators' representatives indicated that the situation with regard to shortages started to subside after the first few months of the pandemic and no significant shortages were reported thereafter. Besides additional disinfection products being made available on the market under the Article 55(1) derogation system, many disinfectant producers increased their operational capacity, thus allowing to meet the increased demand of these products.128 companies were added to the list of suppliers referred to in Article 95 of the BPR either as active substance supplier or product supplier for ethanol and propan-2-ol (119 companies for ethanol and 9 for propan-2-ol). Only 2 Member States requested an extension of the temporary permits granted according to Article 55(1) and less Member States granted emergency permits than at the outset of the pandemic.

[112] https://echa.europa.eu/-/eu-member-states-report-illegal-and-ineffective-disinfectants .