Council of the European Union

Brussels, 7 June 2021
(OR. en)

9582/21

ENV 402
MI 446
AGRI 264
CHIMIE 60

COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	7 June 2021
To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2021) 287 final
Subject:	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

Delegations will find attached document COM(2021) 287 final.

Encl.: COM(2021) 287 final

EUROPEAN
COMMISSION

Brussels, 7.6.2021
COM(2021) 287 final

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

{SWD(2021) 128 final}

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1. INTRODUCTION

Regulation (EU) No 528/2012[1] (hereinafter referred to as the BPR) entered into application on 1 September 2013 and lays down the rules for the making available on the market and use of biocidal products. It repealed Directive 98/8/EC concerning the placing of biocidal products on the market[2] (hereinafter referred to as the BPD).

Biocidal products are designed to control organisms that are harmful to human or animal health or to materials (such as wood). Biocidal products play an important role in the daily life of EU citizens: e.g. insecticides and disinfectants are essential to help control vector-borne diseases, food-borne diseases or hospital-acquired infections. The crucial role of biocidal products for the protection of public health has been particularly highlighted during the COVID-19 pandemic, where disinfecting products are critically important in controlling the spread of the disease.

The BPR establishes a two-step approach in order to achieve its objectives of improving the functioning of the biocidal products market in the EU, while ensuring a high level of protection for human and animal health and the environment[3]. Active substances, which are the ingredients in biocidal products responsible for the action against the target organism(s), must be approved at the Union level or be included into Annex I to the BPR, which lists the so-called "low-risk active substances"[4]. In order to obtain an approval for an active substance, applicants must submit comprehensive dossiers, which are first assessed by an evaluating Member State. The assessment of the evaluating Member State is peer-reviewed by the other Member States representatives within the Biocidal Products Committee (BPC) of the European Chemicals Agency (ECHA). The BPC prepares an opinion of the Agency, which is the basis for the Commission's decision on the approval. Approvals are time-limited, but can be renewed following the evaluation of a renewal application. Active substances are approved for specific product-types as set out in Annex V to the BPR, which defines 22 product-types[5]. Subsequently, biocidal products containing such active substances require an authorisation - at national or Union level - before they can be made available on the market and used.

By way of exception, biocidal products containing active substances that are included in the work programme for the examination of existing biocidal active substances[6] (the "Review

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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] 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).

[3] 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.

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

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

[6] Commission Delegated Regulation (EU) No 1062/2014 (OJ L 294, 10.10.2014, p.1). Existing active substances are active substances which were present on the market in biocidal products on 14 May 2000. Active substances not present on the market in biocidal products on that date are considered new active substances (Article 3(1)(d) and (e) of the BPR).

Programme") can be made available on the market and used according to national legislation of each Member State pending the final decision on the approval of the active substance(s) they contain. Possibilities for derogation from the BPR rules are also foreseen in the event of a danger to public or animal health or the environment: in such situations Member States may grant temporary permits to make available on the market non-authorised products. Member States may also authorise products containing non-approved active substances for the protection of cultural heritage following a derogation granted by the Commission. Lastly, biocidal products containing a new active substance under evaluation may be authorised when certain conditions[7] are met.

This report has been established as required by Article 65(4) of the BPR, according to which the Commission, based on the reports submitted by Member States on the implementation of the BPR in their respective territories, is to draw up a composite report to be submitted to the European Parliament and to the Council. All Member States submitted their reports, except for the Czech Republic. Article 65(3) requires Member States to include in particular information on (i) results of official controls, (ii) poisonings, (iii) adverse environmental effects and (iv) use of nanomaterials. However, no information was provided by Member States on adverse environmental effects, due to the difficulty for Member States to gather this type of data for the first reporting. The Commission will discuss with Member States how to ensure that they will start gathering these data for the next report (due in 2025). The report covers the period from the entry into application of the BPR (1 September 2013) until 31 December 2019. In addition to the information provided by Member States, this report is also based on data extracted from the IT platform[8] used for the submission and assessment of applications and on information contained in the overview report[9] of the fact-finding missions carried out in 2017 and 2018 by the Commission's Directorate-General for Health and Food Safety. This report is accompanied by a Staff Working Document[10] presenting detailed evidence for the findings outlined in the report.

2. STATUS OF THE IMPLEMENTATION OF THE BIOCIDAL PRODUCTS REGULATION

2.1. Active substance approval

Existing active substances in the Review Programme

The Review Programme[11] started under the BPD and was initially foreseen to be completed in 10 years. However, its duration had to be extended twice since it had become apparent that

[7] A full active substance evaluation dossier has been submitted by the evaluating competent authority and it is believed that both the active substance and the biocidal product meet the conditions set out in the BPR (Article 55(2) of the BPR).

[8] Register for Biocidal Products (R4PB) (Article 71 of the BPR).

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

[10] SWD(2021)128

[11] Commission Regulation (EC) No 2032/2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC (OJ L 307, 24.11.2003, p. 1), repealed and replaced by Commission Regulation (EC) No 1451/2007 (OJ L 325, 11.12.2007, p. 3–65).

the evaluations of the application dossiers would not be completed within the initial deadline, first under the BPD[12] - to 14 May 2014 - and then under the BPR[13] - to 31 December 2024.

The execution of the Review Programme still remains affected by significant delays. By 31 December 2019, only 35% of the related work has been completed. Commission decisions approving or not approving active substances were taken for 252 active substance/product-type combinations (of which 179 were adopted under the BPR), while 474 active substance/product-type combinations are still under examination. A steady increase in the number of decisions was recorded between 2014 and 2016, however, a significant decrease occurred in 2017 and 2018, as illustrated in Figure 1.

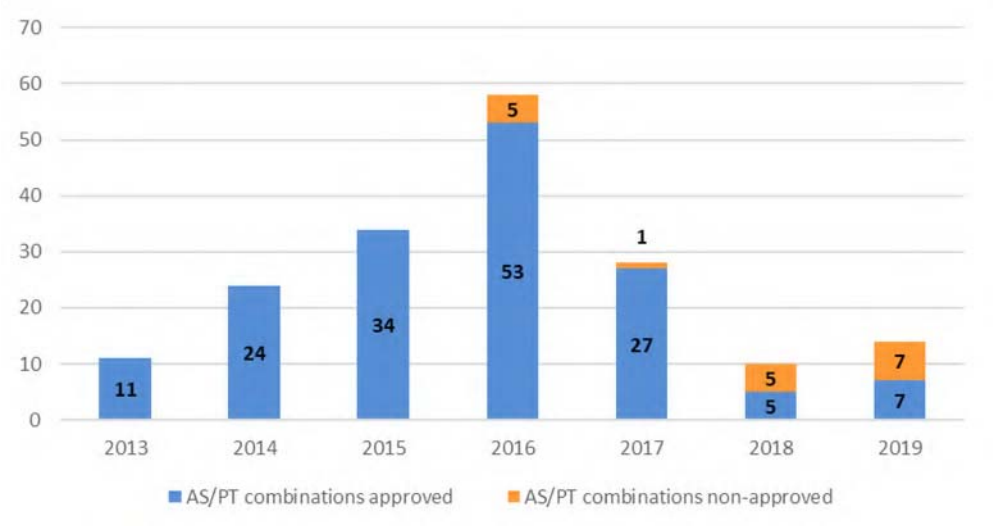

Figure 1: Number of active substance/product-type combinations covered by Commissions decisions on approval/non-approval

This decrease was caused by the falling number of evaluations completed by Member States. While 130 assessment reports were submitted overall by Member States to ECHA between 2014 and 2018, only 1 report was submitted in 2018 and 7 in 2019. The main factors indicated by Member States as causing the delays are: insufficient resources available, delays by applicants in submitting additional data required by Member States during the evaluation, complex technical questions on specific dossiers, evolution of technical guidance, and the adoption of new scientific criteria[14] for the determination of endocrine-disrupting properties.

The Commission and ECHA took action to address the continuous delays in the Review Programme. Already in 2015 the Commission sent letters to Member States, highlighting the importance of completing the Review Programme. In 2017, the Commission initiated discussions with Member States and stakeholders in order to understand the main causes of

[12] Directive 2009/107/EC of the European Parliament and the Council 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)..

[13] Commission Delegated Regulation (EU) No 736/2013 amending Regulation (EU) No 528/2012 as regards the duration of the work programme for examination of existing biocidal active substances (OJ L 204, 31.7.2013, p. 25).

[14] Commission Delegated Regulation (EU) 2017/2100 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 (OJ L 301, 17.11.2017, p. 1).

the delays and to identify possible actions for improvement. A list of actions[15] was agreed in March 2018. In light of the results of a survey among Member States and of the information collected at a workshop of 2019, ECHA proposed an Action Plan[16] that was agreed by the Commission and Member States' Competent Authorities in February 2020.

New active substances

Innovation with regard to new biocidal active substances has been rather limited. Only 10 new active substances were evaluated since the entry into application of the BPR, of which 9 were approved, covering 13 active substance/product-type combinations.

Exclusion and substitution criteria

The BPR introduced exclusion criteria[17] to ensure that the most hazardous active substances are phased out, and substitution criteria for substances presenting a specific concern[18]. In principle, substances meeting the exclusion criteria cannot be approved, unless certain derogation possibilities apply[19]. So far, 3 active substances meeting the exclusion criteria, covering 3 active substance/product-type combinations, and 4 active substances meeting the substitution criteria, covering 9 active substance/product-type combinations were not approved. 21 active substances meeting the exclusion criteria[20], covering 24 active substance/product-type combinations, and 20 active substances meeting the substitution criteria covering 37 active substance/product-type combinations are approved. Of the approved active substances meeting the exclusion criteria, 9 are rodenticides, which are deemed essential to control a danger to human, animal health or the environment in the absence of sufficiently effective alternatives; for the other 12 active substances the transitional provisions in Article 90(2) of the BPR applied, according to which the decisions on approval had to be taken on the basis of the former BPD, which did not contain exclusion criteria. To date, it is not yet possible to assess whether the exclusion and substitution criteria are a driver for the substitution of hazardous substances with safer alternatives. Nevertheless, the exclusion criteria provide a disincentive to apply for renewal of approval, since no application for renewal was submitted for 6 active substances meeting the exclusion criteria and 2 active substances meeting the substitution criteria.

2.2. Product authorisation

As a consequence of the delays in the Review Programme, the majority of the products on the market (several tens of thousands) still fall under national legislations, which are very diverse among Member States. In many Member States only a notification[21] is necessary before making the products available on the market, while in others products need to be authorised.

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

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

[17] See Article 5(1) of the BPR.

[18] See Article 10(1) of the BPR.

[19] See Article 5(2) of the BPR for the grounds for derogation.

[20] 10 active substances are rodenticides, and the others are mostly preservatives (especially wood preservatives) and insecticides.

[21] A notification system implies that no evaluation of the safety or efficacy of a product takes place.

Around 9,000 products are authorised according to the BPR rules following the approval of the active substances contained therein. The majority of products authorised under the BPR were authorised through mutual recognition procedures[22] (around 6,400), and around 2,600 by standalone national authorisation.

As for the review programme for existing active substances, Member States do not respect the deadlines foreseen in the BPR for the various procedures for product authorisation[23]. Especially for mutual recognition, more than 60% of procedures are delayed (about one third of them for 1-2 years and about half for more than 2 years).

The BPR contains specific provisions[24] for the resolution of disagreements that may arise between Member States in the context of mutual recognition procedures and these have worked well so far. Most of the disagreements were settled in the context of the Coordination Group[25], with only 8% of them resulting in a referral to the Commission.

Products containing active substances which are candidates for substitution may only be authorised following a comparative assessment. 1,394 such assessments were performed, of which the great majority (1,289) led to the authorisation being granted without restrictions. Conversely, a simplified procedure is foreseen for the authorisation of products containing active substances which are less harmful. 232 products were authorised so far by the simplified procedure and altogether 474 notifications of making available these products on the market were submitted in the Member States.

138 applications for Union authorisation[26] were submitted so far, of which 106 concerned biocidal product families[27]. The Commission granted 11 Union authorisations, of which one concerned a single product, while the other 10 were for biocidal products families, for a total of 66 products. 183 applications for Union authorisation of so-called same biocidal products[28] have been submitted so far, of which 105 concerned biocidal products families, and 2 authorisations were granted so far. Delays occur also in the Union authorisation procedures, in particular during the assessment by the evaluating Member State, and up to now it was not possible to complete any procedure for Union authorisation within the deadlines: about two thirds are delayed up to one year, about 20% between 1-2 years and about 10 % more than 2 years.

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[22] 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 (Articles 33 to 39 of the BPR).

[23] Monitoring report - authorisation of biocidal products, available at https://circabc.europa.eu/w/browse/a5982814-9d5e-4279-83b1-32ff42fa0792.

[24] See Articles 35 and 36 of the BPR.

[25] The Coordination Group is composed of representatives of Member States and of the Commission, and the secretariat is provided by ECHA (Article 35 of the BPR).

[26] As required by Article 42(3) of the BPR, the Commission submitted a report to the Council and European Parliament on the implementation of the provisions related to Union authorisation until 31 December 2017: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A0342%3AFIN.

[27] A biocidal product family is defined as defined as a group of biocidal products with similar uses, same active substance(s), similar composition and similar levels of risk and efficacy (Article 3(1)(s) of the BPR).

[28] The same biocidal product is identical to another biocidal product or product family which has been authorised or for which an application for authorisation has been submitted.

Derogations from the requirements for authorisation

Between 2014 and 2019, 9 Member States made use of the possibility foreseen in Article 55(1) and granted 135 temporary permits for products that they considered necessary to combat a danger to public or animal health or the environment. As of March 2020, almost all Member States made extensive use of this provision to allow the making available on the market of additional disinfectants needed to address the huge demand to control the spread of COVID-19. Almost 600 notifications of national permits were received by the Commission between March and November 2020. Eight months after the outbreak of the pandemic it can be concluded that this emergency measure in the BPR has allowed to address the unprecedented situation during the COVID-19 pandemic.

Only one Member State granted a provisional authorisation for a product containing a new active substance not yet approved.

By end of 2019, 2 Member States had applied for a derogation pursuant to Article 55(3) of the BPR allowing them to authorise products consisting of in-situ generated nitrogen for the protection of cultural heritage. 5 others applied in 2020. The Commission granted in all cases the derogation.

2.3. Treated articles

Article 58 of the BPR contains provisions on articles which have been treated with or incorporate a biocidal product. A wide range of everyday products are treated with biocidal products, mainly for the purpose of preservation, for instance wood, paints, textile products. Such articles can only be treated with active substances allowed for the relevant product-type (either approved or included in the Review Programme, or for which an application for approval was submitted before September 2013) and have to meet any conditions or restrictions included in the approval of the active substance. The BPR also lays down specific labelling provisions for treated articles.

The controls carried out by Member States between 2014 and 2018[29] indicated that relatively few articles were treated with non-allowed active substances, while non-compliance was higher with respect to the labelling requirements. At least 30% of the articles checked had an incorrect or incomplete label and in two Member States[30] the non-compliance rate was around 80%.

In 2019 Member States executed a coordinated enforcement project of the BPR Subgroup of the Forum[31]. The results[32] showed high compliance with the requirement that only allowed active substances may be used to treat articles. The controls also revealed very high compliance as to the presence of the label when required. However, when considering the

[29] Only 7 Member States reported these data.

[30] Belgium and Sweden.

[31] 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.

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

quality and completeness of the information to be provided on the label, compliance was lower.

In three cases Member States requested the Commission to decide whether a specific product was a biocidal product or treated article[33]. Three such Commission decisions were adopted[34].

2.4. Poisoning incidents

All Member States have appointed poison centres, but record poisoning incidents differently. The total number of incidents recorded[35] varied between 5,248 in 2013 and 14,135 in 2018. The data available indicates that most poisoning incidents involved disinfectants (between 47% and 59% of the incidents recorded yearly) and pest control products (between 39% and 50%). In terms of severity of the incidents, the highest number of fatal or near fatal incidents - involving humans or non-target animals - involved pest control products.

The most relevant exposure route causing incidents is ingestion for children and animals (pets), while for adults inhalation is the most prevalent.

Most Member States have taken measures to educate the general public and raise awareness on the safe use of biocides and on the risks and benefits associated with their use. Encouraging the limited use of biocides and providing information on their safe use (especially of disinfectants and rodenticides) by all Member States could contribute to the prevention of poisoning incidents.

2.5. Enforcement

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. Overall strategies for enforcement of the BPR have been implemented in 20 Member States. In most cases they comprise both proactive (risk-based) controls and reactive controls following complaints.

The compliance rate of the controls carried out by Member States in the reporting period vary greatly between Member States. Some Member States reported high compliance rates with the BPR rules for making products available on the market, while in others compliance rates were low. In some Member States the high rate of non-compliance might be related to the fact that most controls performed followed complaints concerning suspected illegal products on the market.

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[33] In accordance with Article 3(3) of the BPR.

[34] Available at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D0903&from=EN, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015D1985&from=EN and https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32016D0678.

[35] 19 Member States provided relevant data.

The controls on biocidal products containing active substances in the Review Programme still under evaluation and made available on the market according to national legislation of each Member State also revealed very diverse situations in Member States[36].

Only four Member States (Estonia, Poland, Slovakia and Sweden) reported data on controls on residues 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 indicate that in very few cases the residues in food and feed were higher than the allowed maximum residue limit.

Harmonisation of enforcement

The BPR Subgroup of the Forum for the exchange of information on enforcement (BPRS) contributes to the harmonisation of enforcement at EU level. The first harmonised enforcement project, concerning treated articles (see section 2.3), had its operational phase in 2019. The second project, focusing on active substances in biocidal products, is scheduled to have its operational phase in 2022.

2.6. Use of nanomaterials in biocidal products

The BPR incorporates the definition of nanomaterials as laid down in the Commission Recommendation of 18 October 2011[37], and contains specific rules for nanomaterials. 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 has to indicate the name of all nanomaterials contained in the biocidal product.

So far, only two biocidal active substance which are nanomaterials have been approved[38]. Only one product was authorised in 11 Member States[39]. For this product it was concluded that no exposure to the nanoscale primary particles is expected during its use. Two other active substances which are nanomaterials are included within the Review Programme[40].

3. CONCLUSIONS

Eight years after the adoption of the BPR, all provisions are fully operational. The importance of biocides, notably of disinfectants for human hygiene and surface disinfection, was

[36] For further details see SWD(2021)128

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

[38] Pyrogenic, synthetic amorphous, nano, surface treated silicon dioxide, and synthetic amorphous silicon dioxide (nano).

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

[40] In 2020 the application for authorisation of one of them was rejected, due to applicant's failure to pay the fees.

particularly highlighted during the COVID-19 pandemic. The use of the derogation provisions in place under the BPR to react to emergency situations allowed to address the severe shortages in the supply of disinfectants following the steep increase in the demand. The concerted efforts of industry, Member States and the Commission allowed to address the unprecedented situation created by the COVID-19 pandemic.

The main problems identified in this report are the slow progress with the evaluation of active substances included in the Review Programme and the continuous substantial delays in both active substance approval and product authorisation processes. The slow progress with the evaluation of the active substances in the Review Programme, already identified[41] under the BPD, continued after the entry into application of the BPR. Thus, 5 years before the twice extended deadline of 31 December 2024, only 35% of the work programme has been completed.

Very limited innovation on new active substances occurred under the BPR. According to stakeholders, innovation is hindered by high regulatory costs and very long procedures, the relatively small market for biocides and its fragmentation, and the small returns on investment. The slow progress with the Review Programme has been a further disincentive for developing new active substances, since products containing active substances in the Review Programme and still under evaluation can be made available on the market under national rules without having to respect restrictions put in place under the BPR to protect health and environment. Public investment into research could help to increase innovation in this area.

The completion of the Review Programme is thus crucial for the achievement of the objectives of the BPR. The longer the completion of the work programme is delayed, the longer biocidal products containing active substances not yet evaluated for safety and efficacy may be made available on the market. It is therefore imperative to accelerate the pace of the evaluation of existing active substances and complete the Review Programme as soon as possible.

In addition, the Commission receives an increasing number of correspondence from companies, who cannot find an evaluating Member State for the approval or renewal of approval of active substances or for the authorisation of biocidal products (either as reference Member State for mutual recognition or evaluating Member State for Union authorisation), as all Member States approached refuse to do so.

The main reason for all delays observed – and the difficulties for companies finding reference or evaluating Member States accepting applications – is a systemic lack of resources in the Member States.

The Commission therefore calls on Member States to ensure that competent authorities have the appropriate resources to fulfil all their obligations under the BPR within the applicable deadlines. The Commission invites Member States to review the situation of the fees collected for BPR procedures, with regard to the appropriateness of their level and the potential need to ring-fence the revenue derived from them for activities related to the BPR.

[41] Impact assessment accompanying the Proposal for a Regulation of the European Parliament and of the Council concerning the placing on the market and use of biocidal products (COM/2009/0267 final).

The Commission will also launch a call to set up a contract for providing Member States' competent authorities specific technical support to complete their evaluations. A full evaluation of the BPR, planned for 2025, will analyse in-depth the fitness of the current regulatory framework as a basis for deciding on the need for further action.

If Member States do not take the necessary measures to ensure that their authorities can execute the role of evaluating authority for applications for approvals, authorisations and renewals, the regulatory system set out in the BPR cannot function properly.