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Overview report

Biocides

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OVERVIEW REPORT OF A SERIES OF FACT-FINDING MISSIONS ON BIOCIDES IN EU MEMBER STATES 2017-2018

Executive Summary

This overview report provides a summary on the outcome of fact-finding missions carried out in five Member States (MSs) in 2017 and 2018 by the Health and Food Safety Directorate-General of the European Commission. The purpose of these missions was to monitor and assess the implementation of certain provisions of Regulation (EU) No 528/2012 of the European Parliament and of the Council, hereinafter referred to as the Biocidal Products Regulation (BPR).

The objective of the BPR is to improve the functioning of the internal market through the harmonisation of the rules on the making available on the market and use of biocidal products whilst ensuring a high level of protection of both human and animal health and the environment. The evaluation for approval of all biocidal active substances in biocidal products under the Review Programme and the subsequent authorisation of biocides containing these active substances is a key component of the BPR. Transitional arrangements allow biocidal products containing biocidal active substances which have not yet been evaluated under this programme to be made available on the market in MSs, in accordance with national rules for up to three years after the date of approval of the last active substance to be approved in the biocidal product. The review process is scheduled to end in 2024. The majority of biocidal products on the market are currently covered by the transitional arrangements.

The complexity of the review processes, poor quality of dossiers, lack of synchronised procedures and insufficient staff resources including resources wasted on applications which are withdrawn during the evaluation process were among the challenges for MS identified. These increased the burden on resources and, where these are insufficient, result in delays in completing the review process. The use of planning and forecasting tools and improving the quality of dossiers through awareness raising activities and additional pre-submission meetings with applicants were some of the potential good practices identified by which MSs have been able to minimise delays, although these may not be sufficient to avoid the need for additional staff resources.

Enhanced cooperation and coordination within and between the national authorities involved with biocides are essential for a consistent implementation and enforcement of the BPR. Establishing further harmonised EU guidance would facilitate the evaluation process, saving time and resources in the long run. In the meantime, triggering consultations with other MSs is an interim solution to establish a harmonised approach and avoid disagreements at a later stage.

The significant amount of biocidal products which are not authorised for the market where they are made available shows that further attention should be paid to the enforcement of the BPR, particularly aimed at products containing active substances still under evaluation in the Review Programme.

MSs have implemented actions to prevent situations similar to that involving the contamination of eggs with fipronil *from occurring and an EU-wide system of coordinated controls involving biocides, possibly coordinated through the biocides sub-group of the European Chemicals Agency Forum is proposed.*

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ABBREVIATIONS & DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
BPD	Directive 98/8/EC concerning the placing of biocidal products on the market (Biocidal Products Directive)
BPR	Biocidal Products Regulation
CA(s)	Competent Authority(ies)
cMS	concerned Member State
ECHA	European Chemicals Agency
EU	European Union
IT	information technology
IUCLID	International Uniform ChemicaL Information Database
MR	Mutual recognition
MSs	Member State(s)
meta-SPC	meta-Summary of Product Characteristic
PT(s)	Product Type(s)
rMS	reference Member State
R4BP	Register For Biocidal Products
SME	Small and Medium Enterprise
SOP	Standard Operating Procedure
SPC	Summary of Product Characteristic
UA	Union Authorisation

1. INTRODUCTION AND OBJECTIVES

In 2017 and 2018, the Directorate-General for Health and Food Safety of the European Commission undertook a series of fact-finding missions on biocidal products in five Member States (MSs). The objectives of this series was to monitor and assess for the first time the implementation and enforcement 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, hereinafter referred to as the Biocidal Products Regulation (BPR). In particular, this included the assessment of active substances, authorisation of biocidal products and official controls of biocidal products and treated articles.

The scope of the mission series included relevant national legislation, the designation of relevant Competent Authorities (CA(s)), the communication and cooperation within and between these CAs, compliance with the deadlines established under the BPR and official controls on biocidal products and treated articles.

Details of the five missions which were carried out in Hungary (HU), Germany (DE), Spain (ES), Belgium (BE) and the Netherlands (NL) are provided in Annex II. The reports of each of the fact-finding missions are located at: http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm. The individual mission reports, and this report, deal exclusively with applications for authorisation submitted under the BPR, i.e. from 1 September 2013, except where explicitly stated otherwise.

These fact-finding missions were carried out in agreement with the MSs. Relevant legislation and applicable standards are listed in Annex I.

2. BACKGROUND TO THE FACT-FINDING MISSION SERIES

Biocidal products are substances or mixtures of substances used to control harmful organisms in areas other than those related to agricultural production. Biocides include a wide range of products commonly used by both professionals and non-professionals, such as disinfectants, wood preservatives and those for pest control such as rodenticides. They comprise products containing both chemicals and microorganisms as active substances.

The making available on the market and use of biocidal products is regulated in the EU by the BPR, which entered into force on 1 September 2013. Annex V of the BPR classifies biocidal products into 22 product types (PTs), grouped into four main areas.

The BPR was preceded by Directive 98/8/EC concerning the placing of biocidal products on the market, the Biocidal Products Directive (BPD). Prior to this the regulation of biocides was governed by national systems in most EU MSs.

Under the BPR (and previously BPD), the active substances must first be approved at EU level, typically for a period of 10 years, before the biocidal products containing them are authorised by MSs. Companies seeking authorisation for their biocide products can choose to follow one of several different authorisation processes depending on the type of product concerned and the number of countries in which they wish to sell it. A detailed explanation of

the authorisation processes is available on the European Chemicals Agency (ECHA) website: https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr.

The Review Programme, which was established under the BPD and continues under the BPR, is the EU-wide programme of work to examine existing biocidal active substances contained in biocidal products which were on the market on 14 May 2000. Detailed rules for the Review Programme are specified in Regulation (EU) No 1062/2014. The Review Programme is scheduled to be carried out in six phases and is planned to be completed by 2024.

MSs work together in the evaluation and authorisation of biocidal products. The reference MS (rMS) conducts the evaluation on behalf of itself and concerned MS (cMS), i.e. other MSs to which the applicant has applied for authorisation of the same product. Alternatively, applicants can seek Union authorisation (UA), through an administrative act by which the Commission authorises the making available on the market and the use of a biocidal product in the territory of the Union unless otherwise specified, following an evaluation conducted by a rMS.

To ensure the continued availability of biocidal products while the approval and authorisation process are ongoing, transitional measures in the BPR allow those products containing active substances in the Review Programme to continue to be marketed and used subject to national rules, pending the final EU approval decision, and for a period of up to 3 years afterwards. National legislation laying down a system or practice on the making available on the market and use of biocidal products was in place in all MSs visited. To date, most of the biocidal products available on the market of the MSs visited continue to be covered by such national systems or practices established prior to the BPR (about 85% in BE and NL).

The ECHA operates an EU Register for Biocidal Products (R4BP), a dedicated information technology (IT) platform which is used for submitting applications and for exchanging data and information between the applicant, ECHA, MS CAs and the European Commission.

3. OVERVIEW OF MAIN FINDINGS AND CONCLUSIONS

3.1. Aspects of the evaluation for the approval of active substances

1. Most of the MSs visited (NL, ES, BE and DE) had to evaluate existing active substances/PT combinations under the first and second priority list of the review programme (the deadlines for providing the draft assessment report to ECHA were 31/12/2015 and 31/12/2016, respectively). Considering both lists together, at the time of the fact-finding missions, the percentage of applications for which the evaluations were not concluded on time ranged from 12.5% (NL) to 40% (ES). As a result, it is anticipated that there will be delays in completing the evaluations of the third priority list, which have a deadline of 2018.

2. The MSs visited highlighted the following issues which contribute to the current delays in the pending applications:

a. The poor quality of dossiers submitted by applicants, resulting in multiple requests for additional data. In most cases, the deadline for submitting the requested additional data is missed. One MS emphasised the importance that all parties involved in the assessment of active substances respect all the established procedures at each stage of the evaluation process.
b. The requirement introduced in 2018 to broaden the scope of evaluation to include the possible endocrine disrupting properties of active substances and the need to re-visit previously finalised evaluations. At the time of the missions, there was no Guidance Document in this area. The European Commission, ECHA and European Food Safety Authority were still developing joint scientific guidance, which was agreed and published in June 2018;
c. The active substance evaluation process under the BPR and the harmonised classification of active substances under the Classification, packaging and labelling of substances and mixtures Regulation (Regulation (EU) No 1272/2008 on classification, labelling and packaging of substances and mixtures) are not synchronised. In addition, differences in the formats of dossiers required for these two regulations are not harmonised, which leads to additional work for both applicants and evaluators;
d. Wasting resources on evaluation of applications for active substances/PT combinations which the applicant later withdraws during the evaluation process;
e. The complexity and timetable for the approval process combined with the factors above, place a considerable burden on resources and can lead to delays in completing the evaluations.

3. MS acknowledged that delays in completing the different phases of the approval process would prolong the period during which biocides products containing active substances which have gone through the extensive and costly evaluation process will compete on the market with others containing active substances not yet approved – potentially including those which might not satisfy the relevant requirements of the BPR.

4. In order to reduce the delays, without having to significantly increase the resources available, MSs suggested during the fact finding missions minimising the burden of evaluation under the current review programme and then conducting a more detailed evaluation, if required, when the approvals of the active substances/PT combinations are renewed in future.

5. The interested parties and CAs met during the fact-finding missions emphasised that the implementation of the BPR is currently resource intensive for all parties involved, while limited resources are available for innovation and ongoing projects do not include research for new biocidal active substances. The interested parties in the NL noted that during the past 15 years only 10 new actives substances were developed and stressed that innovation is essential.

6. In all MSs visited, there was national legislation laying down implementing powers and establishing a fee framework. In some cases, there is a national system where fees

received from applicants are managed by the CA for biocides, which allows for better adaptation of staff resources to the needs of the planned workload (i.e. the hiring or reallocation of staff).

Challenges identified by MSs

The poor quality dossiers submitted by applicants results in multiple requests for additional data. In most cases, the deadline foreseen for the submission of additional data is exceeded, resulting in delayed decision making.

The non-synchronised procedures with other policy areas (i.e. harmonised classification under the classification, packaging and labelling of substances and mixtures Regulation) prevent the evaluating CAs from finalising the evaluations under the BPR on time.

The evaluation of the possible endocrine disrupting properties of active substances will result in previously finalised evaluations being revisited, further postponing the submission of the assessment report to ECHA.

The above-mentioned factors are causing challenges and delays in the evaluation of applications for approval of active substances.

Insufficient staff resources to timely deliver the assessment of the applications of active substance approval.

On a more general note, the biocidal products on the market of MSs containing those active substances for which the evaluation is delayed are not evaluated under the BPR in order to demonstrate their safety and efficacy. In addition, a level playing field is not established for different companies operating in the same PT market, since their products are subject to very different regulatory regimes (BPR versus national systems).

3.2. Authorisation of Biocidal products

7. Four of the MSs visited (HU, BE, ES and NL) operate a national system of authorisation and notification for biocides established prior to the BPD and BPR. One MS (DE) requires that all biocidal products containing existing active substances must be notified during the transitional period. Maintaining such a system creates work in addition to the implementation of the BPR by processing applications and/or notifications and, when the transitional period under the BPR expires for existing authorisations, to ensure that these are withdrawn. In BE, the current national authorisation and notification systems will be combined into a single registration system in order to free additional staff resources to conduct work relevant to the BPR.

8. Product authorisation, including the maintenance of the national authorisation/registration system of biocidal products under the transitional measures of the BPR and product authorisation under the BPR, as well as the life-cycle management of BPR authorisations (i.e. applications for changes and renewals) represents the main

workload relating to biocides for all MSs visited. The volume of work on product authorisations is likely to increase, in line with any increase in active substance/PT approvals, as well as due to a renewal of already authorised products (e.g. PT 14 and PT 8 products). The upcoming renewal of PT 8 products by 2020, which will require full evaluations in most cases, will result in a doubling of the number of applications to be processed in some MSs (DE).

9. Two MSs (NL and DE) have developed planning tools to predict their future workload. In DE, the central CA conducts both a multi-year and annual planning, in conjunction with the evaluating authorities, to estimate the likely future workload under the BPR. This tool facilitates a reasonably accurate assessment of the time needed for the various work steps. In the NL, a planning and forecasting IT tool has been implemented, allowing fast adaptations of resources if required.

10. In the NL, although the number of applications received was in line with their forecast, the complexity of the applications for biocidal product families was much higher than expected and required more staff resources, which could only be increased in a controlled manner over several years. This complexity of the applications has also been reported by other MSs (DE, ES, BE) as a key element requiring more resources. The NL reported that an application for a biocidal product family requires twice as much time - in working hours - to evaluate compared to a single product. DE indicated that while there are typically 20 efficacy studies for a single product, there can be over 150 for some families of disinfectants. This complexity has resulted in some MSs in a backlog of the evaluations of applications with significant delays.

11. Internally developed databases/IT tools are used in most individual authorities involved in the evaluation and authorisation processes. In some cases spread-sheets or hard copies are used. An electronic system dedicated to biocides facilitates checking compliance with the deadlines, monitoring trends and identifying bottlenecks in the system. However, some internal tools are not compatible with ECHA IT tools and the handling of the applications results in double work (NL). None of the MSs visited where more than one authority is involved in the evaluation work have established a common IT system to track applications, which leads to some inherent inefficiency. In DE, such a system is at an early stage of development.

12. Most MSs have either experienced difficulties causing delays to meet the legal deadlines during the evaluation work of biocidal products (ES, NL, BE) or indicated concerns about their continued ability to respect deadlines under the BPR (DE), simply due to the significant additional workload to cope with. They highlighted the following issues causing most of the delays:

    a. The completeness and quality of product dossiers. As the majority of applicants are Small and Medium Enterprises (SMEs), many of them lack in-house expertise in preparing biocidal product dossiers. While MSs could rigidly adhere to deadlines and refuse applications, they prefer to allow applicants more time to submit

additional data in order to avoid the significant commercial consequences for applicants of a negative decision. This means in practice that the suspension periods for validation or evaluation (the 90 and 180-day periods, respectively) are frequently extended, leading to delayed decision making, while decisions are based on more and/or better data. At the same time, this approach avoids appeal procedures, which would create additional workload for the CAs.

b. The difficulties linked to the handling of complex applications for biocidal product families, for which the workload is a multiple of that of a single product, but the deadlines under the BPR are the same. The complexity of some families also makes the commenting phase during product authorisation (e.g. mutual recognition (MR) or Union authorisation (UA) very challenging. All MSs referred to the working party of the Coordination Group on the biocidal product families, as a way to amend the existing Guidance Document and to better define the criteria to assess biocidal product families, which is essential to address this issue.

c. There is insufficient guidance, or insufficiently clear guidance, for the evaluation of the applications in some specific areas (e.g. test methods for determining the efficacy of biocides for the majority of PTs). Sometimes these issues are not solved at the approval of active substances stage and have to be solved at product authorisation stage. The CAs appreciated ECHA's role in developing a range of very useful Guidance Documents, but MSs visited highlighted an urgent need to develop and agree on additional guidance (including for in-situ generated active substances). However, MSs emphasised that the current workload (NL, ES, HU) and in some cases (DE) the focus on meeting deadlines under the BPR means that they are now doing much less research work in the biocides area, which is also necessary for developing harmonised EU guidance. Since guidance development and its agreement process could take a number of years, some of the MSs visited (BE, DE) address this issue through discussions at pre-submission meetings and following e-consultations with other MSs as an ad-hoc, short-term solution.

d. MSs highlighted that in the case that an authorisation holder requests an amendment to an authorisation, the distinction between major and minor changes is not sufficiently well defined in the Annex to Commission Implementing Regulation (EU) No 354/2013. This results in applicants submitting requests for minor changes for issues that the authorities consider to be major changes. As the time period for processing minor changes is shorter, this makes these applications difficult to be completed within the time permitted.

e. Limited staff resources and inexperienced staff (due to staff turnover) were often significant factors of delays. Three MSs (ES, BE and NL) had shortages of staff and two (BE and NL) were in the process of recruiting new staff and reallocating existing human resources. In DE, the same CAs deal with other similar regulatory files (e.g. chemicals, plant protection products and Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures which gives some flexibility to cope with peaks in workload (up to 10% of additional unforeseen biocide evaluation work was estimated as possible to be undertaken annually). The NL planned to move staff working as Plant Protection Products

assessors to biocides. ES and BE stressed that their available resources were not sufficient to cope with the biocides workload due to the high number of biocides registered in their national system to be maintained and the work to be performed under the BPR. DE stated that although they could handle the biocides evaluations at the time of the mission, the variability in workload, coupled with the intense focus on meeting deadlines was leading to an increasingly stressful environment.

f. Administrative issues with the IT tools were also mentioned including:
   - some issues related to the handling and monitoring of the applications with internal (national) IT tools that lead to inefficiencies (paragraph 15);
   - the links between associated files in R4BP, which do not always work and must be established manually, which is very time-consuming;
   - the mandatory use of the International Uniform Chemical Information Database (IUCLID) format is cumbersome both for the CAs and the applicants causing delays.

13. Internal peer review systems have been established in four MSs (HU, BE, NL and DE) to ensure quality and consistency among the evaluations of different applications, but also consistency with the outcomes of EU-level discussions e.g. from the Article 35 Coordination Group.

14. All MSs established a system to give advice to applicants. Information on the internet and answers to questions are provided in the national language and partially or fully in English. Experts from the CA answer questions generally within 10 to 15 days. Stakeholders met during the fact-finding mission series were satisfied with the quality of the information provided. Meetings organised with applicants prior to submission of a dossier are common practice in the MSs visited. As an example, applicants in the NL can request a meeting before starting the dossier preparation. Additional pre-submission meetings can take place when the biocidal product dossier is almost ready for submission. These two tools help applicants to prepare better quality dossiers and also the CA to save time during the evaluation process. The MSs visited organise workshops regularly and actively take part in interested parties' events to provide information about biocides.

15. HU and DE do not charge any fee for pre-submission meetings. BE charge a fee for these meetings, which is fully refunded in cases where an application is subsequently submitted. The latter practice might prevent a situation reported by HU that, in some cases, applicants do not make a submission after these meetings.

16. MSs have no specific procedures to support SMEs.

17. The interested parties and CAs met during the fact-finding missions emphasised that the implementation of the BPR is currently resource intensive, particularly for SMEs. The interested parties in ES indicated that delays in granting authorisations due to the lack of sufficient staff resources is an issue. Pre-submission meetings and activities should be

encouraged before dossier preparation. They also highlighted the importance of active participation of MS authorities in the development of the lacking EU guidance.

3.2.1. Union Authorisation

18. MSs recognise the UA as an important tool of the BPR. Those MSs acting as evaluating CA highlighted that the overall timeline of the peer review process is very tight due to, in particular, the extensive consultation and the number of comments received from the rest of MSs. For the other MSs, the peer review process involves providing comments on the assessment made by the evaluating CA and contributing to establishing the Summary of Product Characteristics (SPC). HU indicated that while ECHA and the evaluating MS can, other MS cannot charge the applicant a fee for UAs.

19. The NL is in charge of 60% of all UA requests for the entire EU. ES has not agreed to take the role of evaluating CA for UA procedures due to a lack of resources. BE indicated that while resources are limited, they had prioritised their involvement in UA work, both as an evaluating CA and as a participant in the UA peer-review process. They recognise this process as an important part of the implementation of the BPR, and an opportunity for staff to contribute to, and learn from, this work.

20. Apart from the delays for the evaluating CA explained in paragraph 27, the linguistic checks of the SPC, in particular in the case of biocidal product families, was another difficulty identified by the MSs visited.

3.2.2. Authorisation by mutual recognition

21. Both mutual MR in sequence and MR in parallel are tools of the BPR widely used by applicants.

22. Most MSs visited had delays in granting the national authorisations resulting from the MR procedures. MSs reported that delays were mainly related to the limited human resources (NL) and to the quality of the translations of the SPC provided by the applicants (BE). All MSs faced challenges with procedures of MR, since they consider that the 90-day period for MR is challenging (particularly for biocidal product families).

23. Many MR applications are processed late due to delays in the rMS, which the cMS cannot control. In some cases, these delays may exceed the limit of three years foreseen under Article 89 (2) of the BPR. This even includes some on-going MR applications submitted under the BPD (now almost seven years old), which remain under evaluation by the rMS.

24. MSs emphasised that for MR applications they are not conducting a full re-evaluation, except where the quality of the first assessment is so poor as to make commenting upon it of limited value (DE).

25. The updated Standard Operating Procedures (SOPs) for MR in parallel and in sequence, applicable from January 2018 are difficult to apply due to the tight deadlines (NL, DE).

In DE the commenting period can be too short to reach a consensus by all relevant national authorities involved. BE considered though that the SOPs are useful and give both cMS and the rMS a reasonable chance to complete their work within the 90-day period.

26. There has been an increasing number of referrals to the Article 35 coordination group in recent years (2013 to 2017). Since all MSs are involved in reaching an agreement, they all have to invest significant resources in the Coordination Group activities. DE was responsible for one third of all referrals and DE sees the submission of referrals as improving the standard of the evaluation, and hence the level of safety during biocide use in all EU MSs. Moreover, it ensures consistency between the outcome of applications for national authorisation and MR applications (avoiding different conditions of use and risk mitigation measures, and possibly different levels of protection for the users).

3.2.3. Simplified authorisation

27. MSs reported some delays in the evaluation of applications for simplified authorisation due to procedural reasons and limited human resources (NL). Applicants often do not address sufficiently the eligibility criteria specified in Article 25 of the BPR for their biocidal product under the simplified procedure. This leads to incomplete data in the application and, as a consequence, to the application being withdrawn by the applicant (DE), rejected by the evaluating CA (ES) or simply delayed.

28. In the case of notifications, most MSs have always accepted the work done by other MS and the NL only checks the notifications if they did not recently approve a product with the same active substance.

Good practices

Where the CAs deal with other regulatory files synergies and re-allocation of staff help the CA for biocides to cope with peaks in workload or unforeseen evaluation work.

A planning and forecasting IT tool (NL) and multi-year and annual planning (DE) help with planning future workloads and adjusting staff resources needs.

Internal peer review systems help to ensure quality and consistency among the evaluations of different applications, as well as with the outcomes of EU-level discussions (e.g. agreements of the coordination group at EU level).

Pre-application support such as organising dossier preparatory and pre-submission meetings or disseminating information at stakeholders' events help applicants to prepare better quality dossiers and MS CAs to save time during the evaluation process.

Challenges identified by MSs

The authorisation processes place a substantial burden on staff resources and this can contribute to delays in the evaluation of applications and limit cooperate at EU level. The workload is likely to increase further with an increase in active substance/PT approvals, and due to applications for changes to, or renewal of, already authorised products. There is an improper balance between staff resources and workload to be managed.

Incomplete and low quality dossiers result in the suspension of the process causing frequent extension of validation or evaluation, and delayed decision making. The quality of the translations of the SPC provided by the applicants may also delay the national authorisation.

Complex applications for biocidal product families represent an unmanageable workload for the evaluating CAs as the same deadlines apply as for single biocidal products. Their complexity also makes the commenting phase during product authorisation (e.g. MR or peer review under UA) very challenging and time consuming.

In MSs, internal procedures to coordinate the decision making process by all relevant national authorities involved in the MR phase or in the peer review process may cause delays to comply with deadlines of EU procedures.

The submission of referrals (e.g. in order to align the outcome of the assessment for purely national applications and MR applications) may increase the workload of the Coordination Group, in which MSs have to invest a significant amount of resources.

3.3. Official controls on Biocidal products and treated articles

29. The wide range of biocide products means they are typically included in controls covering a range of legislation e.g. chemicals, food and environmental safety and classification, packaging and labelling of substances and mixtures. As a result, the effective enforcement of the BPR requires mechanisms to be in place to facilitate the exchange of information, enhance cooperation and ensure a harmonised approach by the CAs involved.

30. Control activities in the visited MSs generally include professional use of biocidal products and treated articles and are based on annual, risk based control programmes. These programmes can comprise planned controls, projects focusing on a specific theme (e.g. treated articles) and targeted controls in response to intelligence. Most MSs cover both biocidal products and treated articles. BE did not cover the placing on the market of treated articles as the CA considered more guidance/training would be needed at EU level. Controls take place at various levels of the supply chain from import and manufacturing through to distribution and use. The NL also has dedicated projects to control on-line sales of biocidal products and treated articles. Checklists are used, and standardised reports are completed after controls in all MSs visited.

31. In all the MSs visited, the staff conducting official controls of biocides have a technical qualification and receive regular training to keep them up-to-date. Knowledge and expertise is regularly shared at internal meetings in the NL. In HU, inspectors have access to a decision tree developed by the CA for biocides to guide them in determining if a biocide can be legally marketed.

32. The number of controls varies between MSs from about 1 000 to over 5 000 checks annually. The non-compliance level varies in the MSs visited (e.g. 7 to 25% in BE, 10% in HU and 36% in the NL) and was reported to be the highest (over 80%) in one particular case regarding treated articles in the region visited in DE. The enforcement authorities in the NL identified a higher number of non-compliances for some PT1 and PT3 products (50%). Most of the non-compliant cases were found among products regulated under transitional national law. In DE, there are no detailed statistics on the number of controls on biocidal products and treated articles at either *Länder* or federal level.

33. Information regarding biocidal products is available from a single source in two MSs (BE and NL). In three MSs (HU, DE, ES), there is more than one source of publicly available information on the biocidal products that may be legally made available on the market and used. In DE, the involved CAs believe that controls could be more efficient by consolidating the lists and making all lists fully searchable. A single national, regularly updated, publicly available database provides information on authorised biocides in BE and NL.

34. Training and registration of key business operators is mandatory in only two MSs (ES and NL) of the five MSs visited. These tools help to better plan and to ensure a more effective enforcement of the BPR.

35. In ES, professional users involved with the use of most disinfectants, preservatives, rodenticides, insecticides, attractants and repellents are subject to mandatory training. Training courses are standardised and subject to approval by the autonomous communities, who are in charge of the enforcement of the BPR. The training is followed by an exam and a certificate is issued. Regular refreshment courses are required to continue the biocidal activity. The autonomous communities maintain public registers of biocidal establishments (including manufacturers of biocidal products) and services (e.g. PCOs). In the NL, professional users applying PT8, 14, 18 and 19 products and farmers using PT14 products must be trained and certified.

36. Despite their longstanding national systems, the NL and BE reported that they had to deal with a significant number of non-authorised products made available on their markets and used during the transition period. A project dedicated to detect non-authorised biocides was carried out in the NL between 2009 and 2014 and over 1 000 non-authorised biocides were detected on the market. This resulted in 687 new applications for product authorisation and in the withdrawal of the non-authorised

products from the market. The NL and BE stated that such biocidal products are often sourced from neighbouring MSs and from the internet.

37. In BE, the issue of borderline products was highlighted. As an example, in a retail shop visited by the mission team, some packages of shampoo for dogs were authorised as biocidal products while other packages were authorised as a veterinary medicine. In another case in the same shop, some packages of a product to control moles were authorised as biocidal products, while others were not. Such cases are challenging for inspectors to judge and require coordination. A register with all the decisions was under development, which would be accessible to all inspectors and ensure a consistent approach over time and between inspectors. Cooperation with the entity responsible for authorisation of Biocidal products on how to proceed is also needed.

38. Formulation analysis of biocidal products was not systematically included in the control programmes of MSs, except for HU and BE. The autonomous community visited in Spain was planning to carry out formulation analysis in 2018. The region visited in DE stated that they have access to the necessary laboratory capacity if they need to act in the case of suspicion.

39. The mission team discussed, in three MSs, the responses to the occurrence of contamination of table eggs and poultry meat with *fipronil* substance and the actions taken or planned to prevent that similar cases happen. All MSs had taken, and were planning to take, further actions in response to this incident. These measures included:

    a. Updating cooperation between authorities, the communication strategy and the Food Safety Incident Management Plan;
    b. More awareness raising and enhanced self-control of operators, improvement of processing alerts from consumers and companies and early signaling of trends and enhanced innovation;
    c. Exploring the possibility to oblige private laboratories to report non-compliances of analysis requested by operators within their own checks;
    d. Considering the risk associated with *fipronil* when developing the control programme for the following year and broaden the range of residues to analyse, as well as the number and type of foodstuffs of animal origin analysed, to detect the fraudulent use of biocides and similar substances;
    e. Suggesting an EU wide system of coordinated controls involving biocides, possibly coordinated through the ECHA Biocides Forum.

40. Besides the information detailed above, MSs have the following systems in place in addition to the requirements of the BPR and contributing to its enforcement:

    a. In BE, authorisation holders are legally obliged to declare their annual sales volumes of biocides to the CA. Comprehensive summary data on the sales of products, and the active substances contained therein are published, broken down by group, PT and professional/amateur use. The CA highlighted that this

information is very useful for risk management and for planning their risk-based control programme;

b. In ES, a national system of rapid information exchange has been in place since 1997 to report incidences with chemical products, which is also used for biocides. In addition, the national poison centre informs the CA for biocides about accidents reported to them where biocidal products are involved. These data are included in the report of the Spanish CA prepared according to Article 65 of the BPR.

c. BE included some aspects relevant to the sustainable use of biocides in their National Action Plan under Directive 2009/128/EC on the sustainable use of pesticides.

d. In the NL, as a requirement of authorised use, Integrated Pest Management certification is mandatory for outdoor use of rodenticides. The obligation to follow the Integrated Pest Management principles is specified in the Summary of Product Characteristics of these products. The CA compiled a publicly available Integrated Pest Management handbook to help users.

Good practices

A single national, regularly updated, fully searchable database providing information on the biocidal products that can be legally made available on the market and used facilitates enforcement activities by inspectors and makes controls more efficient.

Registration, training and certification of the relevant operators at national (or regional) level contribute to a robust control system for biocides. Declaring the annual sales volumes of biocides to the CA could also be useful for planning risk-based control programmes.

Including formulation analysis of biocidal products systematically in the control programmes of MSs helps to better enforce the BPR and detect some non-compliant cases (e.g. fipronil), particularly during the transitional period.

Detailed statistics at MS level, including the number of controls and the non-compliance rates is a key to assess the implementation and enforcement of the BPR at both national and EU level (Article 65 of the BPR).

A national system of rapid information exchange to report incidences help to take consistent enforcement actions by all the relevant CAs throughout the country.

Internal meetings, a register of previous cases and similar instruments accessible to all inspectors contribute to a more consistent approach over time, particularly for borderline cases.

Specific targeted actions to detect non-authorised biocidal products which have not been authorised for the markets they are made available and withdraw them from the market is a key enforcement action under the BPR, which ensures a level playing field for compliant business operators.

Challenges identified by MSs

MSs need to control a wide range of products and often several authorities are in charge of controls requiring enhanced cooperation and coordination which takes extra time, or even leads to an inconsistent enforcement throughout the country.

Borderline products which are or can be subject to different legislation and treated articles are challenging to control and require targeted actions;

The significant amount of non-authorised products still present on the market in some MSs shows that special attention should be paid to the implementation and enforcement of the BPR, particularly during the transitional period.

3.4. Cooperation between Competent Authorities at EU level

41. All MSs highlighted the importance of the work at EU level in order to achieve EU-wide harmonisation and consistency in the approval of active substances and the authorisation of biocidal products. In particular, working groups managed and meetings hosted by ECHA and participation in this work were mentioned. The coordinating activity of ECHA fora ensures that staff are fully up to date on scientific developments so as to provide high quality evaluation work and provides networking and learning opportunities. Participation in EU-coordinated work (e.g. meetings, guidance development) can save time in the long run. Three MSs (DE, BE and NL) stated they actively contribute to ECHA and other EU meetings and two MSs (HU and ES) have difficulties to attend all meetings due to a lack of resources.

Good practices

Devoting resources to EU level work coordinated by ECHA and the pro-active contribution of MSs help to implement the BPR in a more consistent way throughout the EU, as well as saving time and resources for the CA in the long run.

4. ACTION TAKEN BY THE COMMISSION SERVICES

42. A workshop to share experiences with MS CAs gained during the biocides fact-finding missions and identified in this overview report was organised from 19 to 21 June 2019. The targeted goal of the workshop was to:

    a. take ownership of the findings and conclusions of the fact finding missions and use them to improve the implementation of the BPR;
    b. gain an understanding of good practices in the EU and how these may be adopted in their activities;

c. discuss weaknesses and recurring problems in MS, with the aim of identifying possible solutions at MS and EU level.

43. The conclusions and proposals of the biocides workshop:

a. <u>General aspects</u>

- Organise workshops and training to address specific needs and share experiences and good practices;
- Increase knowledge of applicants and consultants (presentations at conferences; 'training for dummies' and using social media/website of CAs; invite applicants' associations for EU level meetings);
- Have access to all relevant information for evaluation on a single location including technical guidance, relevant European Court of Justice rulings; and establish "precedents list" to help to deal with similar cases;
- Link the implementation of biocides EU legal framework to political hot topics and public health priorities to underline the benefits of having sufficient staff resources for biocides (e.g. highlighting delays in the Review Program as a health issue causing the presence of non-regulated, potentially dangerous chemicals on the EU market);
- MSs, in particular smaller MSs could focus resources on specific expertise and being selected for evaluation according to their expertise (e.g. efficacy or impact on health and environment and dealing with certain PTs);
- New guidance should not be applied to on-going applications ("do not evaluate yesterday's work with today's standards");
- Exchange of experts between CAs;
- Exchange of experiences on how to estimate upcoming workload for authorities in order to allocate efficiently resources;
- Improve the method to estimate future workload and allocation of resources and experts; CAs to share standard time periods applied for the evaluation of certain parts of applications and applicants to notify their intentions for submitting applications and ECHA to extend it's planning for active substances and UAs;
- Harmonise fee structures between Member States covering work sharing of evaluation between CAs;
- The European Commission and ECHA to support CAs in complex cases (technical, procedural and legal).

b. Approval of active substances

- Introduce the possibility of having a co-rapporteur for the evaluation of an active substance;
- Consider longer approval periods for non-hazardous active substances so the resources can be focused on the substances with a higher risk profile;
- Earlier identification of key points in the evaluation and focus on these points;
- Establish task forces of experts of several CAs for the evaluation of groups of active substances having a similar chemical and/or risk profile;
- The European Commission to take the lead to have a better coordination and steering of the review process and to develop a strategy that focuses on the completion of the Review Program of biocidal active substances;
- ECHA to identify the lacking guidance that is most urgent, to provide more support to MSs during the evaluation process, to facilitate the closer cooperation between the staff involved in more pieces of legislation (biocides and classification, packaging and labelling of substances and mixtures) and work towards aligning tools and formats for biocides and classification, packaging and labelling of substances and mixtures legislation.

c. Authorisation of biocidal products

- In order to reduce the number of poor quality applications:
  - Arrange mandatory pre-submission meetings with applicants (with a possibility to charge a fee);
  - Set criteria/develop guidance on quality standards for applications and refusals;
  - Charge applicants actual costs (no fixed fee).
- Facilitate the authorisation process by addressing horizontal issues at the active substance evaluation process;
- Differentiate in the evaluation process between professional and general public uses;
- Have UA system open to all PTs, make the UA system more accessible to SMEs; and it should be verified whether a fee can be charged for peer review by experts of CAs in the Biocidal Product Committee and for checking the quality of translations provided by applicants;
- Improve the translation process of UA documents.

d. Controls and enforcement of the BPR

- The major challenges for controls are the wide range of products within the scope of the BPR, borderline products and to tackle the presence on the EU market of illegal biocidal products, of those products which are not registered nor have a notification number. The enforcement of the EU rules for treated articles and internet sales of biocides are also difficult to control.

- Proposals to improve enforcement:
  - Provide harmonised guidance for controls, and offer training for inspectors;
  - Improve the cooperation between the different authorities responsible for the different parts of the EU chemicals legislation;
  - Develop an annual work plan with clear priorities for controls based on consulting the relevant authorities;
  - Ensure a harmonised approach for all the actors involved in enforcement with a feedback mechanism after completing the inspections and ensure consistency by disseminating information between authorities regarding problematic cases;
  - Exchange inspectors between CAs
  - Provide tools for inspectors to access easily information on national and BPR authorisations, EU legislation and guidance, to check labels and to communicate confidential information between inspectors of different authorities.
  - Treated articles and internet sales to be addressed in the Biocides subgroup of the Forum;
  - Communicate existing rapid alert systems and train inspectors on how to use them.

5. ACTION PLANNED BY THE COMMISSION SERVICES

44. Review to the proposals developed during the Biocides workshop held in June 2019 that would contribute to a better implementation of the BPR.

45. Encourage MSs to further exchange good practices, including bilateral cooperation (training and expertise sharing).

46. Remind MSs of the legal obligation to have sufficient staff to implement the BPR, so that the obligations in Article 81 of the BPR and the legal deadlines for active substance approval and product authorisation are respected. A timely delivery in these two interlinked procedures is essential to ensure a high level of protection of both human and animal health, and the environment, as well as to establish a level playing field among business operators.

47. Continue monitoring the respect of timelines included in the BPR approval of active substances and biocidal product authorisation procedures and discussing with Member States and applicants the possibilities to improve the situation.

48. Draw the attention of all interested parties to implement all the actions already agreed at the meeting of the Commission Expert Group 'Competent Authorities for Biocidal Products (Regulation (EU) 528/2012)' in March 2018 in order to accelerate the review programme (CA-March18-Doc.5.1a - Final - Actions for AS review programme.pdf).

49. Encourage MSs to actively engage with ECHA as foreseen in the Action Plan to revive the Review Programme to submit long-stalled assessment reports for the peer review phase.

50. Draw the attention of all interested parties to implement all the actions already agreed at Competent Authorities for Biocidal Products meeting in July 2017 concerning the management of the "stop of the clock" for the management of product authorisation (CA-July17-Doc.4.2 - Final - Handling the stop of the clock.doc)

51. Support further the development of an EU-wide system of coordinated controls, through the ECHA Biocides Sub-group of Forum by EU coordinated enforcement projects and actions.

52. Foster innovation in the biocides sector, involving public and private sector, while stimulating the substitution goal in the BPR.

6. MATTERS FOR CONSIDERATION BY MEMBER STATES

The good practices identified should be considered by MSs and use the experience adjusted to their circumstances.

Active contribution and cooperation at work carried out under the BPR at EU level.

7. ACKNOWLEDGEMENTS

The European Commission would like to acknowledge the contribution of the National Experts who gave both their time and their expertise in contributing to the success of this mission series. National Experts are CA officials that work in the specific area being evaluated, and work with Commission officials as part of the mission team for the duration of the specific mission. Their detailed knowledge of technical aspects of the legislation and control systems contributed greatly to the value-added component of the fact-finding mission series.

Finally, the European Commission would like to thank all the CA officials and applicants' representatives met during the mission series for their cooperation and positive approach, which greatly facilitated the evaluation work.

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 1272/2008	OJ L 353, 31.12.2008, p. 1-1355	Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 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
Reg. 528/2012	OJ L 167, 27.6.2012, p. 1-123	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
Reg. 354/2013	OJ L 109, 19.4.2013, p. 4–13	Commission Implementing Regulation (EU) No 354/2013 of 18 April 2013 on changes of biocidal products authorised in accordance with Regulation (EU) No 528/2012 of the European Parliament and of the Council
Reg. 1062/2014	OJ L 294, 10.10.2014, p. 1–34	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
Reg. 492/2014	OJ L 139, 14.5.2014, p. 1–6	Commission Delegated Regulation (EU) No 492/2014 of 7 March 2014 supplementing Regulation (EU) No 528/2012 of the European Parliament and of the Council as regards the rules for the renewal of authorisations of biocidal products subject to mutual recognition

ANNEX II: DETAILS OF MISSIONS UNDERTAKEN

Member State	Dates of mission	SANTE reference number
Hungary	23/11/17 – 01/12/18	2017-6014
Germany	17/01/18 – 26/01/18	2018-6357
Spain	20/02/18 – 01/03/2018	2018-6358
Belgium	19/04/2018 – 27/04/2018	2018-6361
Netherlands	04/06/2018 – 13/06/2018	2018-6360

The individual mission reports and Competent Authority comments on draft reports are at http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm.

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