In response to information provided by the competent authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.
Executive Summary

This report describes the outcome of a fact finding mission in Spain, carried out from 20 February to 1 March 2018 as part of the published Directorate-General for Health and Food Safety programme for 2018.

The objective of the mission was to investigate the implementation by the Competent Authorities of certain aspects 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.

There has been a well-structured system in place for registration of biocides since the 1980s, and the Competent Authorities have a good level of control over the making available on the market and use of biocides: all biocidal products placed on the market are authorised or notified under either transitional national or European Union legislation, establishments manufacturing, packaging and distributing biocides are registered, a system for training professional users of biocides is in place and enforcement is well established. In addition, there was good communication observed between the authorities.

Although the system for evaluation of active substances and the authorisation of biocides is well established and structured, and compliance with the legal deadlines has been improving, there remain significant delays.

The authorities highlighted that the complexity of the different types of biocidal products, the necessity to review the evaluation of endocrine disruptive properties of active substances and the emerging trend for applicants to seek authorisation for large and diverse ranges of biocidal products under a single biocidal family product application are challenges to comply with the deadlines of the Biocidal Product Regulation.

As this was a fact-finding mission, no recommendations were made.
### Abbreviations and Definitions Used in This Report

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<th>Abbreviation</th>
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<tr>
<td>AEMPS</td>
<td>Spanish Agency of Medicines and Medical Devices</td>
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<td>BPC</td>
<td>Biocidal Products Committee</td>
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<td>BPD</td>
<td>Directive 98/8/EC concerning the placing of biocidal products on the market (Biocidal Products Directive)</td>
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<td>BPR</td>
<td>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 (Biocidal Products Regulation)</td>
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<td>CA(s)</td>
<td>Competent authority(ies)</td>
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<td>CLP</td>
<td>Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures</td>
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<td>cMS</td>
<td>concerned Member State</td>
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<td>DG</td>
<td>Directorate-General</td>
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<td>ECHA</td>
<td>European Chemicals Agency</td>
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<td>EU</td>
<td>European Union</td>
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<td>FTE(s)</td>
<td>Full Time Equivalent(s)</td>
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<td>INIA</td>
<td>National Institute for Agricultural Research and Experimentation</td>
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<td>IT</td>
<td>information technology</td>
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<td>MAPAMA</td>
<td>Ministry of Agriculture and Fisheries, Food and Environment</td>
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<td>MS</td>
<td>Member State(s)</td>
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<td>MSSSI</td>
<td>Ministry of Health, Social Services and Equality</td>
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<td>MR</td>
<td>Mutual Recognition</td>
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<td>PT(s)</td>
<td>Product Type(s)</td>
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<td>rMS</td>
<td>reference Member State</td>
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<td>R4BP</td>
<td>Register For Biocidal Products</td>
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<td>SIRIPQ</td>
<td>System of Rapid Information Exchange of Chemical Products</td>
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<td>SME(s)</td>
<td>Small and Medium Enterprise(s)</td>
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<td>SOP(s)</td>
<td>Standard Operating Procedure(s)</td>
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<td>WG</td>
<td>Working Group</td>
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1. INTRODUCTION

This was the third mission of the Directorate-General for Health and Food Safety’s (DG Health and Food Safety) mission series on biocidal products. The mission formed part of the DG Health and Food Safety’s planned programme for 2018 and took place from 20 February to 1 March 2018.

The mission team comprised two staff members from DG Health and Food Safety, one expert from a European Union (EU) Member State (MS) and one observer from the European Chemicals Agency (ECHA).

The Ministry of Health, Social Services and Equality (MSSSI) is the main Competent Authority (CA) for the authorisation of biocidal products and treated articles in Spain and a representative of the MSSSI accompanied the team throughout the mission.

In pursuit of the mission's objectives, an opening meeting was held with the MSSSI, the Ministry of Agriculture and Fisheries, Food and Environment (MAPAMA), and the Spanish Agency of Medicines and Medical Devices (AEMPS) in Madrid. At this meeting, the mission team confirmed the objectives and scope of, and itinerary for, the mission.

2. OBJECTIVES AND SCOPE

The objective of the mission was to investigate the implementation of certain provisions 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).

The scope of the mission included relevant national legislation, the designation of relevant CAs, the communication and co-operation within and between these CAs, compliance with the deadlines established under the BPR and official controls on biocidal products and treated articles.

This report deals exclusively with applications for authorisation under the BPR, i.e. from 1 September 2013, except where explicitly stated otherwise.

During the mission, a series of meetings were held with central and Andalusian authorities to gain an understanding of the system of controls under the BPR. The mission team participated in a control at a retailer of biocides and met with representatives of applicants seeking authorisation for biocidal products and other stakeholders involved with biocides.

3. LEGAL BASIS

This fact-finding mission was carried out in agreement with the CA. Relevant legislation and applicable standards are listed in Annex I.
4. BACKGROUND

Pesticides comprise both plant protection products and biocidal products, commonly referred to as biocides. Plant protection products are used to control harmful organisms on plants, while biocides are substances or mixtures of substances used in order to control harmful organisms in other areas. Biocides include a wide range of commonly used products used by both professional and non-professional users, such as disinfectants, wood preservatives and pest control products such as rodenticides. They comprise both chemical and biological products.

Biocides are regulated in the EU under the BPR, which entered into force on 1 September 2013, and which regulates the making available on the market and use of biocidal products. The BPR was preceded by Directive 98/8/EC concerning the placing of biocidal products on the market (BPD).

Annex V of the BPR classifies biocidal products into 22 product types (PTs), grouped in four main areas. There are five PTs in Group 1, which comprises disinfectants for use in a range of areas such as human hygiene and veterinary hygiene. Group 2 includes PTs 6-13, all of which act as preservatives e.g. wood preservatives. Group 3 comprises biocides for pest controls and includes PTs 14-20. Group 4 comprises PTs 21 and 22, under the umbrella of “other” biocidal products.

Under both the BPD and BPR, biocidal products must be authorised before they can be placed on the market and used. This process is explained in detail on the European Chemicals Agency (ECHA) website https://echa.europa.eu/regulations/biocidal-products-regulation/understanding-bpr. This is a two-step process, where first the active substance must be approved at EU level, typically for 10 years, and subsequently, the products are authorised at MS level.

However, biocidal products had been placed on the market and used for many years prior to the BPD and BPR. Therefore, under the transitional measures, biocidal products containing active substances in the Review Programme can continue to be made available on the market and used subject to national laws pending the final decision on the EU approval of the active substance, and for up to three years afterwards. The Review Programme is the EU-wide programme of work for the examination of existing biocidal active substances contained in biocidal products. It was established under the BPD and continues under the BPR. Existing active substances are those substances which were on the market on 14 May 2000 as an active substance in a biocidal product.

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. Union authorisation means 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.
Applicants may seek authorisation either for a single biocidal product, or a group of similar biocidal products, referred to as a biocidal family.

Under Article 35 of the BPR, ECHA have established a co-ordination group, at which disagreements related to mutual recognition (MR) are discussed with a view to reaching agreement by consensus.

Active substances with certain intrinsic hazardous properties are approved for shorter periods, thus prompting the more frequent review of these active substances and their associated biocidal products. Consequently, while some active substances had not yet been approved for the first time at an EU level and their associated products evaluated and authorised at MS level, the re-evaluation and re-approval of these more hazardous active substances, and the subsequent re-evaluation and re-authorisation of the associated products, has already begun.

ECHA holds data relating to the approval of biocidal active substances and the authorisation of biocidal products, which was used in the course of this mission and in the mission report. This data is held in the Register for Biocidal Products (R4BP), a dedicated IT platform which is used for submitting applications and for exchanging data and information between the applicant, ECHA, MS CAs and the European Commission.

The MSSSI stated that at the time of the mission, 452 biocides had been authorised in Spain under the BPD and the BPR.

The CAs have no data on the volumes, or value, of biocides marketed and used in Spain.

5. **FINDINGS**

5.1. **NATIONAL LEGISLATION**

**Legal Requirements**

Article 291 of the Treaty on the Functioning of the EU

**Findings**

1. Article 23 of Royal Decree 1054/2002 designates the competent authorities for biocides.

2. Spain has maintained the national registration system for biocides which is in place since 1983 to ensure the continued protection of public health during the transitional period. This is allowed under Article 89 of the BPR.

3. The following national legislation is applicable during the transitional period:

   a. Royal Decree 3349/1983 on the technical-health regulations for the manufacture, sale and use of pesticides;
   b. Articles 32-37 of the General Health Law (nº14/1986) of 25 April establishes the legal basis for infringements and sanctions;
c. Royal Decree 1054/2002 regulating the evaluation process for the registration, authorisation and marketing of biocides and developing the infringements and sanctions applicable to biocidal product;

d. Article 33 of the Law 53/2002 on fiscal measures regulates fees applicable for biocides;

e. Order SCO/3269/2006 on the registration and operation of the Register of Establishments and Pesticide Services;

f. Royal Decree 830/2010 establishing rules on training to carry out treatments with biocides;

g. Royal Decree 865/2003 establishing hygienic-sanitary criteria for the prevention and control of Legionellosis.


5.2. COMPETENT AUTHORITIES

Legal Requirements

Article 81 of the BPR on Competent authorities

Findings

5.2.1.1. Designation of Competent Authorities

5. In Spain, the MSSSI and the MAPAMA are the CAs for biocidal products and treated articles.

6. More specifically, under the MSSSI
   a. the General Directorate of Public Health, Quality and Innovation is responsible for most assessment work and coordinates all biocides related tasks and
   b. the AEMPS is responsible for the efficacy assessment of products that get in contact with human skin and disinfectants in hospitals (PT 1 and PT19).

7. In addition,
   a. the General Directorate of Quality and Environmental Evaluation, and Natural Environment of the MAPAMA is responsible for environmental assessments and
   b. the General Directorate for Health of Agricultural Production of the MAPAMA is responsible for the efficacy assessment regarding animal safety (PT 3 and PT19).

8. The National Institute for Agricultural Research and Experimentation (INIA), a public institution and Tragsatec, belonging to a group of state owned companies, provide technical assistance for evaluations of active substances and biocidal products.
9. The Autonomous Communities (regions) are responsible for all matters relating to enforcement under the BPR. In Andalusia, the Regional Health Department is the CA for biocides.

5.2.1.2. Resources

10. The MSSSI has 35 full time equivalent (FTE) staff dedicated to biocides work, including external, technical and administrative staff. The two directorates of MAPAMA allocated 14.6 FTE combined and AEMPS 6.8 FTE to biocides activities. External staff work on a contract basis.

11. The biocides team of MSSSI are responsible for the management, assessment, authorisation, and registration of both active substances and biocidal products. MAPAMA has staff dedicated to biocides who deal with the evaluation of both active substances and biocidal products. In all cases, professional staff have university degrees in relevant areas such as chemistry, biology, toxicology, human and veterinary medicine, pharmacy and environmental science.

12. In addition, three technical expert staff of INIA provide assistance to the MSSSI and another three provide assistance to the MAPAMA. They perform the efficacy, toxicological properties, human exposure and physico-chemical assessments for MSSSI and environmental assessments for MAPAMA. Twelve and five Tragsatec experts staff are allocated at MSSSI and MAPAMA, respectively. They provide assistance in human exposure, toxicity/eco-toxicity, physico-chemical properties, analytical methods and efficacy evaluations.

13. Although external assistance is available to some extent, MSSSI and MAPAMA stated that, in general, the available resources are not sufficient for the biocides workload. This is due to the high number of biocides registered in the national registration system to be maintained and to cope with the work under the BPR.

14. In Andalusia, staff conducting official controls under chemicals legislation, including biocides, have a technical qualification and receive regular training to keep them up to date.

5.2.1.3. Organisation of the evaluation and authorisation process

15. In Spain, due to public health related incidents, a national registration system was introduced for biocides in 1983. This system has been, and will be, maintained during the transitional period of the BPR. Biocidal products of Product Types PT1, PT2, PT3, PT4, PT8, PT11 (only against Legionella), PT14, PT18 and PT19 must be registered according to Royal Decree 3349/1983 and PT5, PT6, PT7, PT9, PT10, PT11 (other than uses against Legionella), PT12, PT13, PT15, PT16, PT17, PT20, PT21, PT22, treated articles, nanomaterials and in situ substances/biocidal products must be notified according to Royal Decree 1054/2002.

16. During the transitional period under the BPR, three registers are maintained:
a. Register of the General Directorate of Public Health, Quality and Innovation of the MSSSI for PT2 (except for disinfectants for hospitals), PT4, PT8, PT11 (only against *Legionella*) and PT14 (at the time of the mission all these products were authorised under the BPR), 18,19 (except in livestock environment and in contact with human skin);

b. Register of the AEMPS for PT1, PT 2 (disinfectants for hospitals) and PT19 (repellents and attractants in contact with human skin) and


17. In addition, a notification database is in place during the transitional period for in situ substances, nanomaterials and treated articles and products, hypochlorite and the rest of the product types that are not registered according to the national registration system.

18. Under the BPR, the MSSSI receives the application via the Register for Biocidal Products (R4BP). So far, applications for authorisation of biocidal products under the BPR concerned only biocides with existing active substances and no application was received containing new active substances. The MSSSI receives the application and sends a standardised letter to the applicant to confirm all registered or notified biocidal products in the national database and available on the market in Spain that they wish to get authorised. Then the applicable fee is requested for payment. If a biocide is in the national register, but not notified by the applicant in the confirmation letter, the national authorisation of the product is cancelled to fulfil the requirements of Article 89.3 of the BPR. This is to ensure that where there is no application for authorisation or mutual recognition in parallel and where no request for Union authorisation for the same biocidal product has been submitted, the biocidal product is no longer made available on the market with effect from 180 days after the date of approval of the active substance(s). The use of existing stock may continue for up to 365 days after the approval date of the active substance(s).

19. In the case of biocidal products that are registered or notified according to the national requirements and subsequently authorised under the BPR, the product authorisation according to the national rules is cancelled. The MSSSI issues a cancellation letter to the authorisation holder and the product is removed from the national registers and the notification database.

20. The MSSSI requests the relevant authorities to complete their evaluation by certain deadlines. These deadlines are formally agreed between the authorities at coordination meetings, in order to complete the work by the deadline of the BPR. The MSSSI use a confidential courier service to forward all studies and data related to the application for active substance to the authorities in paper form. The data are shared in electronic format on CD for active substances dossiers and through the R4BP for product authorisation.
21. The MSSSI have developed a working procedure to guide staff in processing applications for authorisation of biocidal products. This includes instructions on the acceptance, validation, evaluation of the applications, granting authorisation and post-authorisation tasks. The procedure for evaluation of active substances is decided on a case by case basis. The MAPAMA organise their biocide work on a case by case basis depending on the dossier and use their internal database for planning. The AEMPS also decides on the procedure on a case by case basis, although a written procedure specifies the main steps.

22. A dedicated co-ordinator within MSSSI is allocated to each application for authorisation.

23. The MSSSI forwards each application to the relevant evaluating authorities for completeness check who then send any request for additional information to the MSSSI. The coordinated request for additional information is sent to the applicant by the MSSSI.

24. The MSSSI developed an in-house customised database to track all product applications. This system facilitates dealing with the numerous tasks and deadlines associated with applications and includes a series of related document templates in Spanish and some in Spanish and English. This database is used to manage applications submitted through the R4BP for on-going cases and a separate one is for biocidal products authorised under the BPR. Some information of the latter database is published on the regularly updated online register (see section 5.5).

25. There are internal peer review systems in the MSSSI and the MAPAMA to ensure the quality and consistency of their evaluations. The AEMPS does not have any such internal peer review system.

5.2.1.4. Planning

26. The applications for active substance evaluations are known a number of years before submission as this work is agreed at EU level under the review programme. This system facilitates long term and a more efficient planning and work practice. Spain currently has over 15 000 biocidal products registered or notified in the national system. The MSSSI stated that their work under the BPR is basically guided by the legal deadlines. They further stated that although they can use external staff, the number of staff assigned to their biocide team is limited which does not allow much flexibility when planning.

5.2.1.5. Advice to applicants

27. The MSSSI have established a helpdesk (e-mail address: biocidas-helpdesk@msssi.es) dedicated to biocides. It has been notified to the Commission in line with Article 81 of the BPR. The helpdesk has been operational since 2013 and provides information on the provisions of the BPR and on certain national requirements for biocides. Information is provided in Spanish and English and questions are generally answered by experts of the MSSSI. The average response time is 15 days and standardised answers are provided to frequent questions.
28. The number of queries has increased sharply from 27 in 2013 to 931 in 2017. Recent questions concern mainly the transitional period of the BPR. As the majority of the interested companies are SMEs, stakeholder associations often act as intermediaries contacting the MSSSI directly and compiling questions and answers.

29. Stakeholders met by the mission team were satisfied with the quality and the content of replies provided by the helpdesk although they would appreciate quicker answers.

5.2.1.6. Co-operation between Competent Authorities at EU level

30. The Spanish authorities consider EU co-operation in the biocides area as well established and important. Although their capacities are limited, the authorities highlighted the importance of the work of these fora.

31. The MSSSI and MAPAMA share responsibility for attending the Standing Committee on Biocidal Products, the meeting of CAs for Biocidal Products, Coordination Group meetings. The MSSSI also attends the Biocidal Products Committee (BPC) and BPR enforcement group. They regularly participate at these meetings representing Spain.

32. The Spanish authorities have a very limited capacity to take part at Working Groups (WGs) of the European Chemicals Agency (ECHA). The MSSSI and MAPAMA are flexible members of the three permanent WGs of the BPC. These WGs deal with efficacy, human health and the environment. The CAs stated that they are trying to follow these meetings remotely via teleconference as they can rarely attend in person due to their heavy workload (see also 5.4).

33. There are also ad-hoc WGs and working parties e.g. the current working party on biocidal product families where Spain is unable to attend although dealing with biocidal product families is challenging for them.

5.3. ASPECTS OF THE APPROVAL OF ACTIVE SUBSTANCES

Legal Requirements

Article 7 of the BPR on the submission and validation of applications

Articles 8 of the BPR on the evaluation of applications

Findings

34. Spain has finalised the evaluation of 13 active substance/PT combinations out of 48 under the biocides review programme and was evaluating another 13 active substance/PT combinations at the time of the mission.

35. Spain had to evaluate nine active substance/PT combinations from the first priority list under the Regulation (EU) No 1062/2014 of which six (67%) have been approved, all within the legal deadline. The remaining combinations were still under evaluation at the time of the mission. Six active substance/PT combinations from the second priority list had to be evaluated out of which three (50%) were approved within the legal deadline and
the remainder were still pending at the time of the mission. The pending active/PT combinations remain under evaluation due to a range of technical issues to resolve. These issues concern identity of active substances, technical equivalence and other technical issues.

36. The MSSSI highlighted the following main issues relevant to this area that contribute to delays:

a. The poor quality of dossiers submitted by applicants results in multiple requests for additional data from applicants, in order to complete the evaluation, with the result that the 180 day period foreseen for the submission of additional data is often exceeded;

b. The active substance evaluation process under the BPR and classification of active substances under Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP) are not synchronised, which leads to delays in finalising evaluations under the BPR. In addition, the format of dossiers under BPR and CLP is not harmonised, which leads to additional work for both applicants and evaluators;

c. The recent EU requirement to broaden the scope of evaluation to include the possible endocrine disrupting properties of active substances. Currently, there are no Guidance Documents in this area, but the Commission, ECHA and EFSA are developing joint scientific guidance;

d. Wasting resources on evaluation of applications for active substances/PT combinations which the applicant later withdraws during the evaluation process.

37. Representatives of applicants seeking authorisation for biocidal products and other stakeholders stated at the meeting with the mission team that no innovations are ongoing for new biocidal active substances. The reasons stated were the long approval procedures and the high costs for submitting active substance applications compared to product prices on the market.

5.4. AUTHORISATION OF BIOCIDAL PRODUCTS

Legal Requirements

Articles 26, 27, 29, 30 and 31 of the BPR on systems of authorisation

Articles 33 and 34 of the BPR on mutual recognition in sequence and in parallel

Article 35 of the BPR on the referral of objections to the co-ordination group

Article 37 of the BPR on derogations from mutual recognition

Article 42 of the BPR on Union authorisation
Articles 47, 48, 49 and 50 of the BPR on the cancellation, review and amendment of authorisations

Article 52 of the BPR on periods of grace

Article 53 of the BPR on parallel trade

Article 55 of the BPR on derogations

Findings

38. Spain is one of the MSs with the highest number of biocidal products authorised under the BPR and BPD. According to ECHA data 466 products were authorised in Spain in January 2018.

39. The MSSSI explained that authorisations and notifications of biocidal products under national legislation, are allowed under the BPR for the transitional period until the decisions on the active substances under the BPR are taken. This creates additional work for the authorities involved in the processing of the applications and notifications. It creates further work when products are evaluated under the BPR, to ensure that existing authorisations are withdrawn. This additional work is one reason for delays with processing applications within the deadlines established under the BPR.

40. This additional workload makes it difficult for Spain to actively participate in some of the working groups on biocides at EU level, for example the working party on biocidal product families, and also technical working groups (see also 5.2.1.6).

41. The workload is also a reason why Spain is not rMS for Union authorisation (see also 5.2.6).

42. The authorities also highlighted a number of points:

   a. MSSSI also explained the difficulties with biocidal product families. Due to the emerging trend for applicants to seek authorisation for large and diverse range of biocidal products under a single biocidal family product application are challenges to comply with the deadlines of the Biocidal Product Regulation. At the time of the mission, Spain had granted eight authorisations of biocidal product families, where Spain acted as cMS.

   b. The evaluation of notifications of experiments or tests under Article 56 of BPR contributes to the workload of the authorities involved. The MSSSI showed examples where notifications had to be evaluated in detail to ensure environmental safety.

43. The mission team met with representatives of applicants seeking authorisation for biocidal products and other stakeholders. They highlighted a number of issues relevant to Spain, including:
a. The high level of technical knowledge of all CAs involved. The experience gained under national legislation has helped to build up this knowledge base. The helpdesk support and the possibility to meet with CAs were considered very useful.

b. The high cost of data generation to gain authorisation under the BPR, relative to market size, and market prices, for many biocides, particularly for SMEs.

c. The delays in granting authorisations in Spain, and their concern that sufficient resources are allocated to biocides evaluation.

d. The usefulness of pre-submission meeting, and their interest that these meetings are facilitated more regularly and before dossier preparation.

e. The difficulty to ensure compliance of imported chemicals and treated articles.

f. The importance of active participation of the Spanish authorities in the development of EU guidance.

5.4.1.1. Union authorisation

44. The MSSSI stated that the procedure for granting Union authorisation is very useful, allowing authorisation across the EU with a smaller workload for them, but the MSSSI acknowledged that they have not yet accepted a rMS role.

45. At the time of the mission, 79 applications had been submitted through R4BP3, but Spain has acted as cMS in all cases. The MSSSI have been requested by several applicants to act as rMS, but the MSSSI rejected these requests stating that they did not have the resources to accept a rMS role.

46. Spain has received four draft Product Assessment Reports / Summary of Product Characteristics for commenting, from those other MS who acted as rMS. The MSSSI stated that they responded in all cases within the EU deadlines.

5.4.1.2. Simplified authorisation

47. Twenty-one notifications for simplified authorisations had been received at the time of the mission, out of which only five had been approved. Another five applications were pending, with the remainder being rejected by the MSSSI, or withdrawn by the applicant.

48. The MSSSI stated that applicants often do not sufficiently understand that they must address the eligibility criteria for the simplified procedure of their biocidal product. This leads to incomplete data in the application and delays or rejections. By way of examples, the MSSSI highlighted an application, where the eco-toxicological classification of the mineral oil in a formulation had to be clarified, and another case where the application did not address the possible sensitising properties of an essential oil, which might cause an allergic response.
5.4.1.3. National authorisation

49. The MSSSI stated that 95 biocidal products were authorised under the procedure for national authorisations. Of these 95 products, 70 were authorised within the deadlines specified by the BPR, and 25 applications exceeded the deadlines, on average by 229 days. The MSSSI explained the reasons for the four applications with the longest delays. The delays of these four applications affect 17 applications in other MSs where the applicant has applied for mutual recognition in parallel.

50. The CAs identified the following reasons for delays with national authorisations:

a. The CAs explained that the ECHA guidelines leave some room for interpretation on whether certain data are required for evaluation, e.g. on whether a particle size test is required or whether a justification is sufficient.

b. In many cases, the CAs considered the quality of the submitted dossier to be low. The majority of applicants are SMEs, many of which lack in-house expertise in preparing biocidal product dossiers. This also applied to applications from large multi-national companies, in one of which there had been data gaps in eight areas. The CAs explained that for over two years they requested several times additional data from the company, until the data package was finally considered complete. Although the EU legal deadline for the company to submit additional data was exceeded by far, the CAs did not reject the applications. One reason is that any non-approval can be appealed by the company, and the matter is submitted to the MSSSI DG for appeals. Any appeals procedure creates additional workload for the CAs.

c. In one example the delays were compounded by the end of temporary contracts of the evaluating staff in INIA.

d. In another example, the CA needed time to identify a suitable model to evaluate human exposure to a product to control termites. The CA stated that due to the large number of different product types, it would be very difficult to include suitable exposure models for each possible type of application in Guidance documents.

5.4.1.4. Authorisation by mutual recognition

51. The MSSSI informed the mission team that 497 applications have been submitted for mutual recognition, including applications for mutual recognition in parallel and in sequence. In these cases Spain is the cMS and has to rely on the rMS. A total of 268 of the applications have been completed and the products authorised. All authorisations of mutual recognition in sequence had been delayed, the large majority of them with delays over 365 days. For mutual recognition in parallel, the MSSSI stated they always submit their comments to the rMS within the legal deadline.
52. The MSSSI stated that the procedures for authorisation by mutual recognition in parallel are very useful, allowing to authorise products on time, and with a reduced workload for the Spanish CAs. The MSSSI stated that also the industry prefers the procedure in parallel to the procedure in sequence, and therefore 88 % of the ongoing applications relate to mutual recognition in parallel.

5.4.1.5. Cancellation, review and amendment of authorisations

53. In cases of adverse data related to an authorised product, the authorisation holder is obliged to notify the CAs without delay. The MSSSI reported that they had received no such notifications.

Renewal of authorisations

54. The MSSSI stated that a large proportion of the products authorised in Spain under BPD and BPR (351 out of 452) are rodenticides (PT 14). The peak of authorisations of rodenticides under the BPD was in 2014. Now that authorisations of rodenticides have to be renewed under BPR, there is another peak workload for these products. A total of 221 applications for authorisation of rodenticides are currently under evaluation or awaiting authorisation. For 96 of these applications, Spain is the rMS.

55. The CA highlighted that the evaluation of rodenticides under BPR has created several problems for them, relating in particular to:

   a. National rules about categories of users which are different from such rules in other Member States;

   b. National risk mitigation measures.

56. Despite the difficulties encountered, the CA stressed that they expected to complete the renewal of rodenticide product authorisations by 1 March 2018, which is the legal deadline set by the CLP Regulation for the implementation of new harmonised classification of the active substances.

57. The MSSSI reported a research study on resistances of rodenticides being carried out in Spain. In addition, the MAPAMA is also carrying out a research project on analytical samples of target organisms.

5.4.6.1. Parallel Trade Permits

58. Spain had received no applications for parallel trade permits and the CAs were not aware of any biocides marketed under parallel trade permits at the time of the mission.

5.4.6.2. Derogations

59. At the time of the mission, Spain had not granted derogations under Article 55 of the BPR.
5.5. Organisation of Official Controls of Biocidal Products and Treated Articles

Legal Requirements

Article 65 of the BPR regarding compliance with requirements and official controls

Findings

60. In Spain, the 17 autonomous communities (regions) and 2 autonomous cities are responsible for the implementation of controls to enforce the BPR.

61. Details of biocides authorised under the national registration system are accessible at [http://www.msssi.gob.es/en/ciudadanos/productos.do?tipo=plaguicidas](http://www.msssi.gob.es/en/ciudadanos/productos.do?tipo=plaguicidas) during the transitional period. Once a product has been re-authorised under the BPR, it is removed from the national register and included in the official register of biocides approved under the BPR which is available at [https://www.msssi.gob.es/ciudadanos/productos.do?tipo=biocidas](https://www.msssi.gob.es/ciudadanos/productos.do?tipo=biocidas).

62. According to Order SCO/3269/2006 the autonomous communities maintain registers of biocidal establishments and services. Manufacturers, packaging, storage and marketing establishments of biocides are subject to registration. In addition, individual or legal entities providing biocidal services must also be registered.

63. As required by Royal Decree 830/2010, professional users of biocides must be trained to carry out treatments with biocides. Staff involved with the use of most disinfectants, preservatives, rodenticides, insecticides, attractants and repellents are subject to training. Training courses are standardised subject to approval by the regions. The training is followed by an exam and a certificate is issued. The certificate does not have an expiry date, but a refreshment course of at least 20 hours is required every five years to continue the biocidal activity.

64. The enforcement activities in Spain are based on annual project plans drafted by each autonomous community. The enforcement activities and related issues are discussed at technical meetings managed by the MSSSI. Autonomous communities decide on their project plans involving biocides depending on their local situation e.g. establishments involved with biocides present in their territory.

65. The planned projects for 2018 include a number of areas to control and Spain will take part of the EU pilot projects planned for 2018-20 regarding treated articles.

66. The national System of Rapid Information Exchange of Chemical Products (SIRIPQ) has been in place since 1997 to report incidences with chemical products and is also used for biocides in Spain.

67. The MSSSI provides biocide related information to the national poison centre to take into account if an accident occurs. In addition, the national poison centre informs the MSSSI
about accidents reported to them where biocidal products are involved. These data are included in the report of the MSSSI prepared according to Article 65 of BPR.

68. The mission team visited Andalusia and noted that

a. Establishments dealing with manufacturing, packaging, storage and trade of biocidal products, furthermore biocidal services and permanent treatment facilities must be registered for PT 2, 4, 8, 11, 14, 18 and 19 biocide products. There are 857 establishments registered in Andalusia most of which are operators providing biocidal services. In 2017, a total of 1957 inspections to 686 establishments and services were carried out and three minor and eight major non-compliances were identified involving manufacturers and service providers, respectively;

b. The mandatory training courses for professional users of biocides must be approved by the regional authority.

c. The controls regarding biocides are organised at three levels: regional, provincial and district and focus on three main tasks: product controls, control of establishments and training of professional users of biocides. Each district selects 20 chemical out of which a maximum of five biocides are checked annually;

d. The controls are planned and coordinated by the regional, subsequently by the provincial level and inspections are carried out by health protection agents of the district level. The health protection agents generally carry out biocides controls combined with other chemical controls e.g. chemical and environmental safety;

e. Control staff regularly receive general and specific training and have procedures available to carry out controls consistently. Internal audits are also carried out;

f. The mission team visited a small biocide manufacturer where the health protection agent explained that regarding biocides they generally request from the manufacturer documentation to fulfil requirements of Article 65.2 (documentation of the manufacturing process including the safety data sheets). They compare the list of biocides handled with the official registers of biocides, check labels of biocides and perform traceability checks.

g. Formulation analysis of biocides to verify whether the product is compliant with the authorised label has not been carried out in Andalusia so far and it is planned for 2018 as a new project.

69. The CAs stated that the risk of fraud cases similar to the one leading to *fipronil* contaminations of food cannot be completely avoided. Nevertheless, the mission team noted that the CAs in Spain have a good level of control over the placing on the market and use of biocides: all biocides placed on the market are authorised or notified under either transitional national or EU legislation, establishments manufacturing, packaging and distributing biocides are registered, a system for training professional users of biocides is in place, and enforcement is well established. In addition, there was good
communication between authorities. The CAs stated that the risk of fraud could be further reduced by more awareness raising and enhanced self-controls by the operators dealing with biocides.

6. **Overall Conclusion**

There has been a well-structured system in place for registration of biocides since the 1980s, and the Competent Authorities have a good level of control over the making available on the market and use of biocides: all biocidal products placed on the market are authorised or notified under either transitional national or European Union legislation, establishments manufacturing, packaging and distributing biocides are registered, a system for training professional users of biocides is in place and enforcement is well established. In addition, there was good communication observed between the authorities.

Although the system for evaluation of active substances and the authorisation of biocides is well established and structured, and compliance with the legal deadlines has been improving, there remain significant delays.

The authorities highlighted that the complexity of the different types of biocidal products, the necessity to review the evaluation of endocrine disruptive properties of active substances and the emerging trend for applicants to seek authorisation for large and diverse ranges of biocidal products under a single biocidal family product application are challenges to comply with the deadlines of the Biocidal Product Regulation.

7. **Closing Meeting**

A closing meeting was held in the MSSSI in Madrid on 1 March 2018 with representatives of MSSSI, MAPAMA, AEMPS and the Regional Health Department of Andalusia. At this meeting, the mission team presented the findings and the preliminary overall conclusion of the mission and CAs provided initial comments.
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