LO STATO DELL'ARTE DELLE AUTORIZZAZIONI DEI PRODOTTI BIOCIDI

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- INAIL
- Dipartimento di medicina, epidemiologia, igiene del lavoro e ambientale

AGENDA

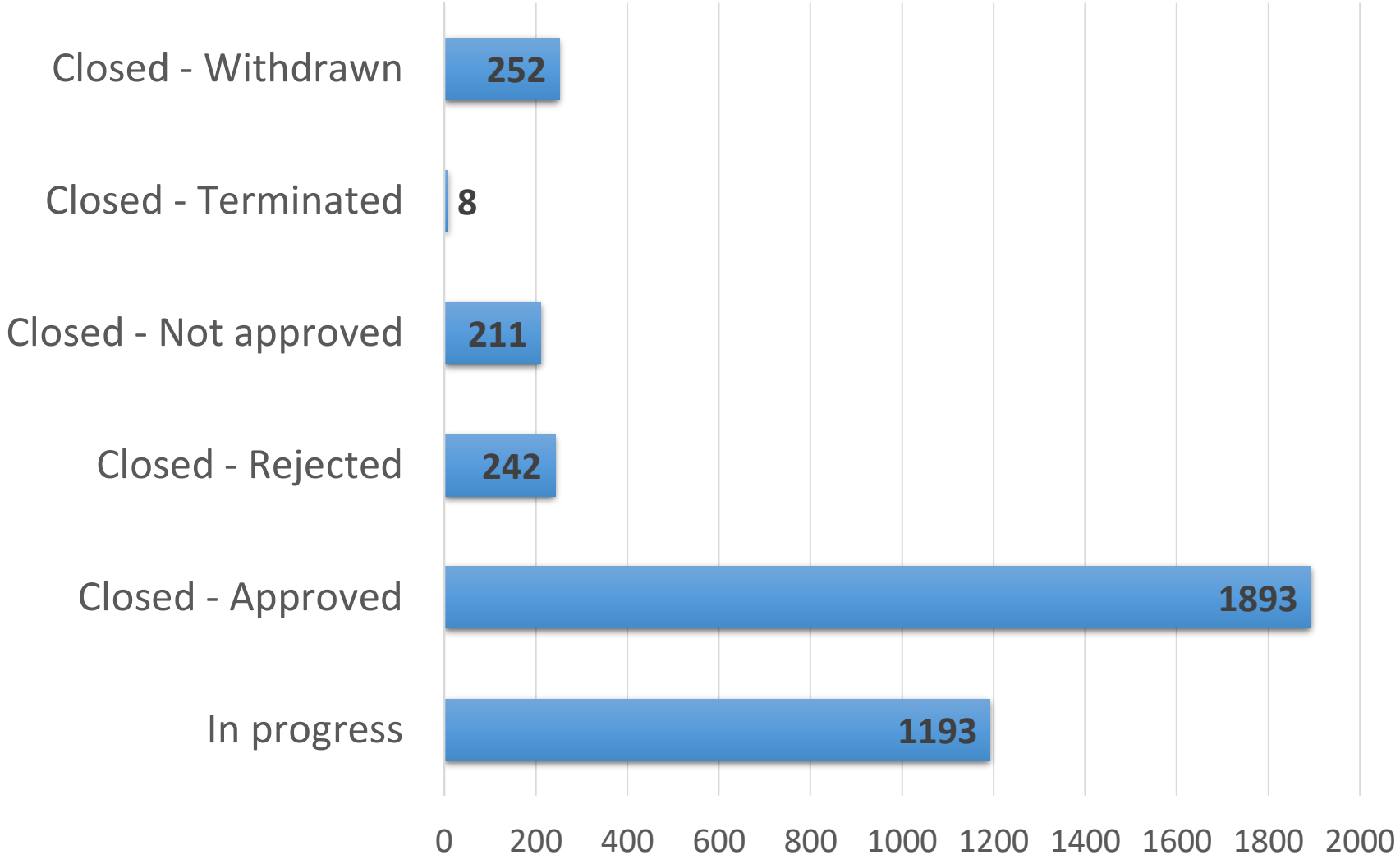
I. Dati

- Richieste
- Autorizzazioni di prodotti

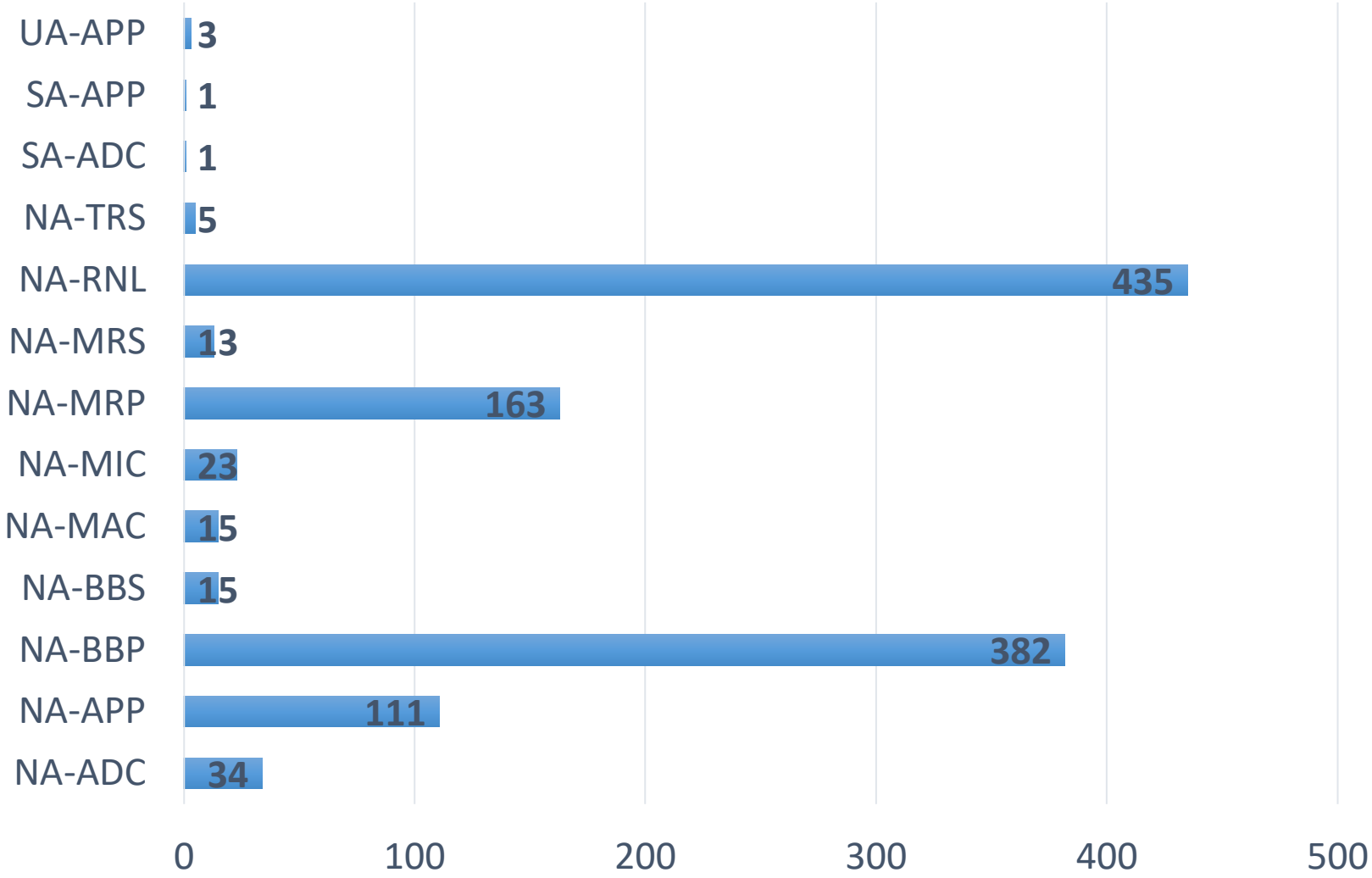
II. Raccomandazioni

- Gruppo di coordinamento

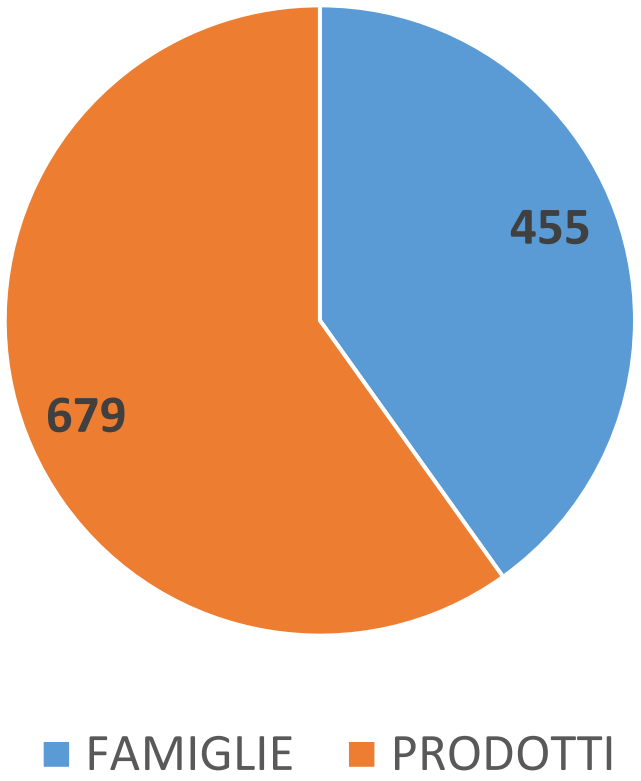
RICHIESTE PRODOTTI BIOCIDI (NA/UA/SA)
(3799 risultati al 31/10/2023)



RICHIESTE IN PROGRESS
(1193 risultati al 31/10/2023)



AUTORIZZAZIONI NAZIONALI PRODOTTI BIOCIDI (1134 attive al 31/10/2023)



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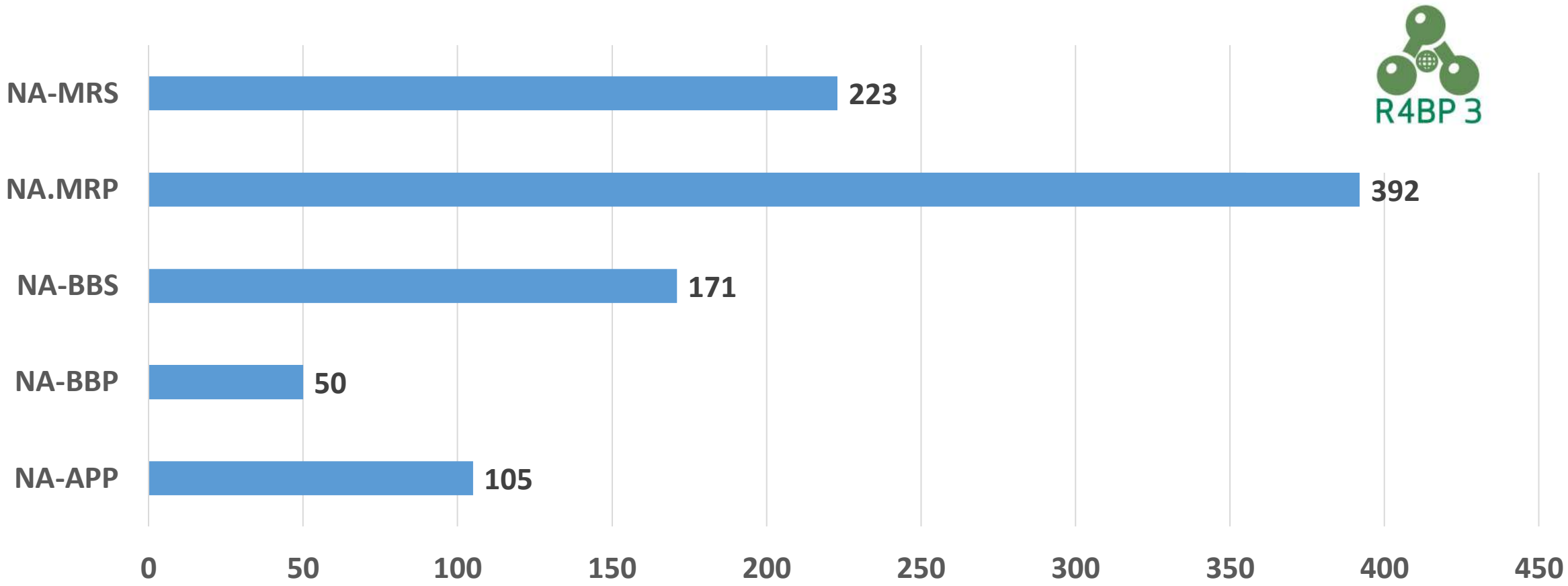

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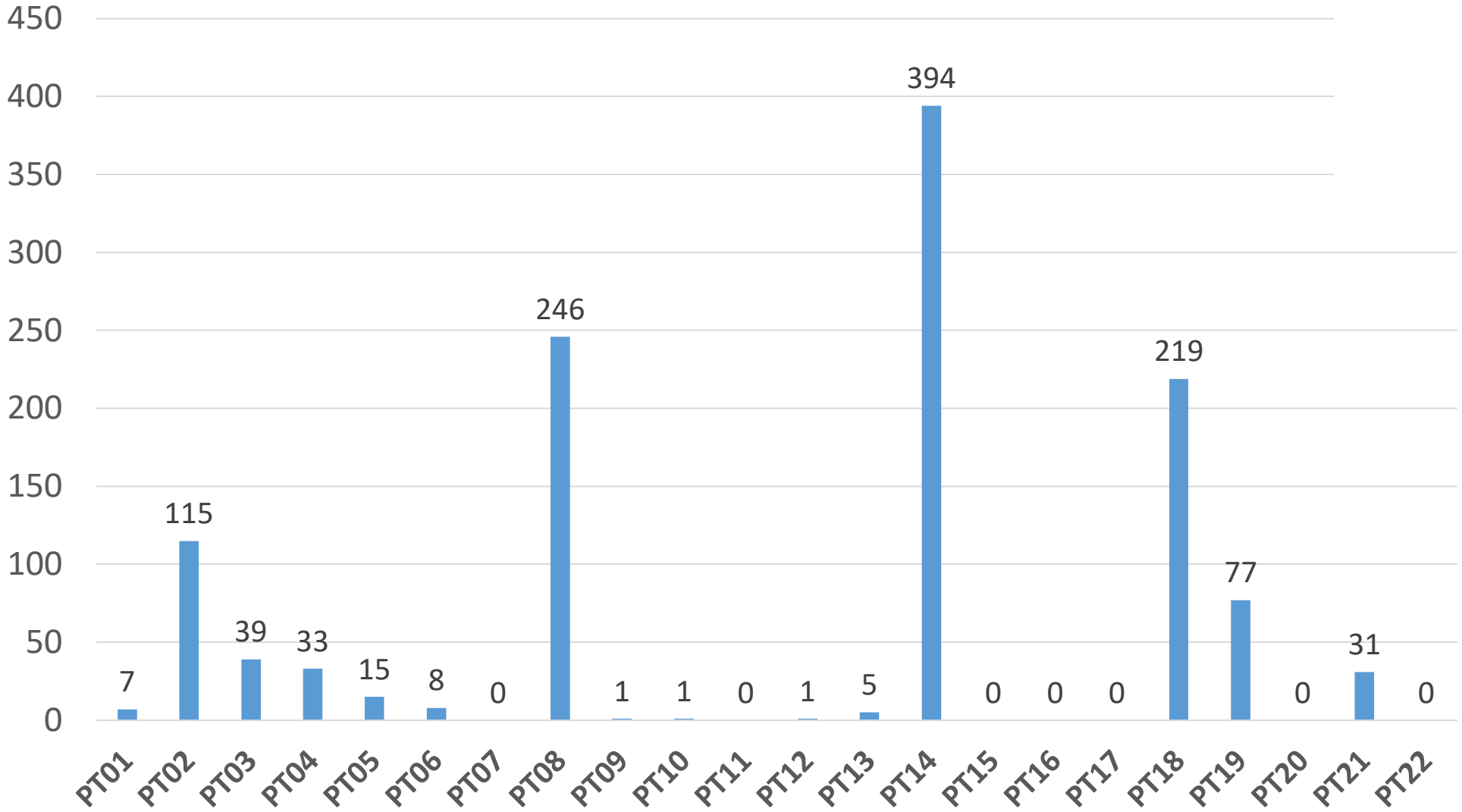
(Tipologia di prodotti al 31/10/2023)



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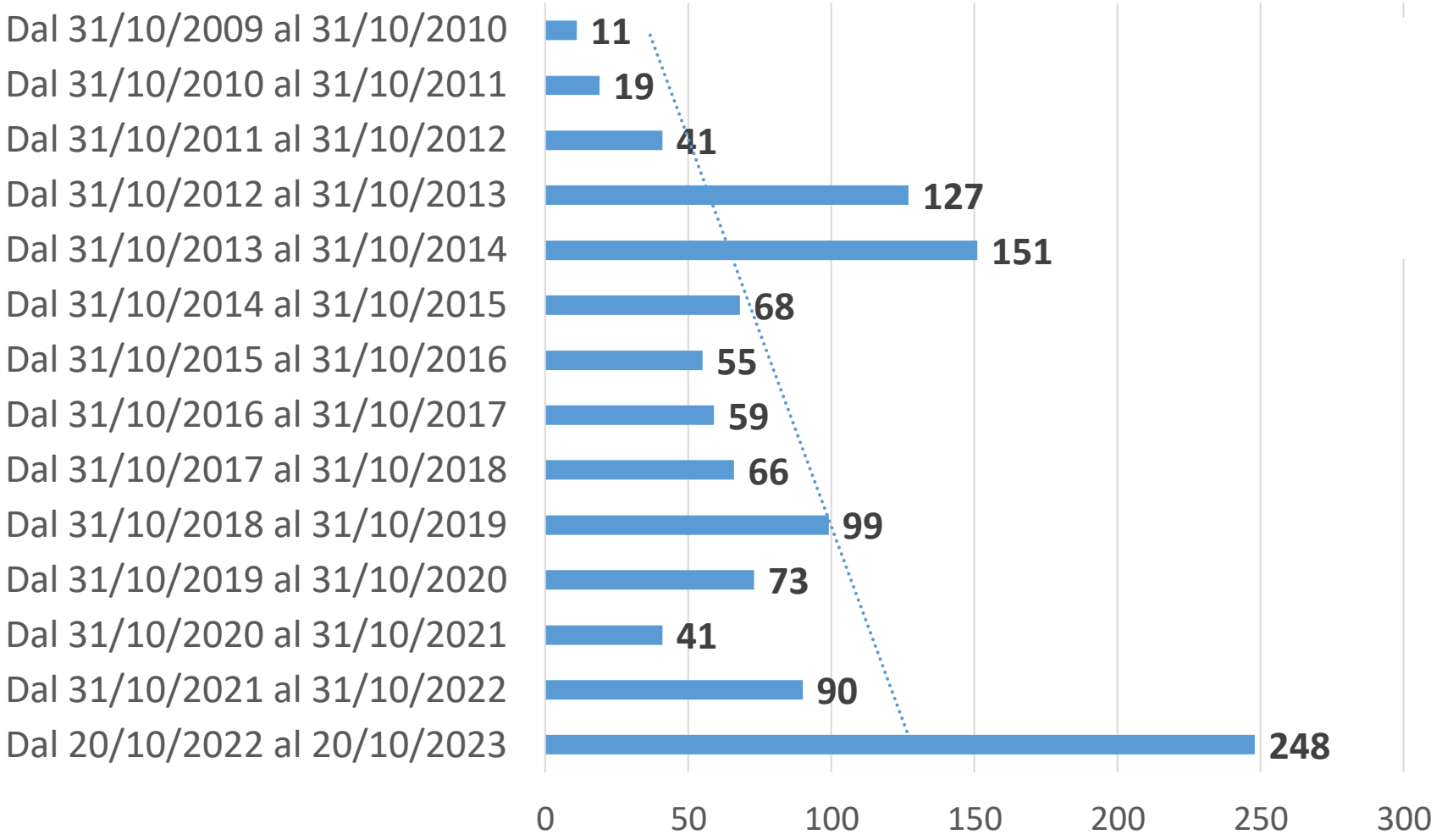
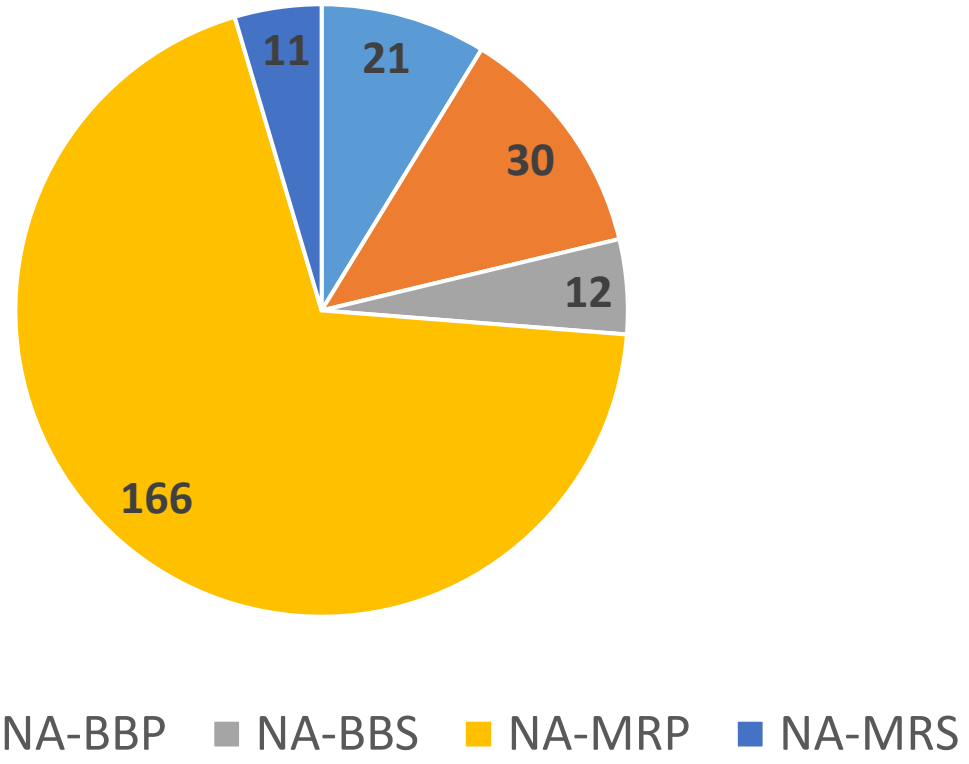


R4BP 3

AUTORIZZAZIONI NAZIONALI PRODOTTI BIOCIDI
(Tipologie di autorizzazione dal 31/10/2022 al 31/10/2023)



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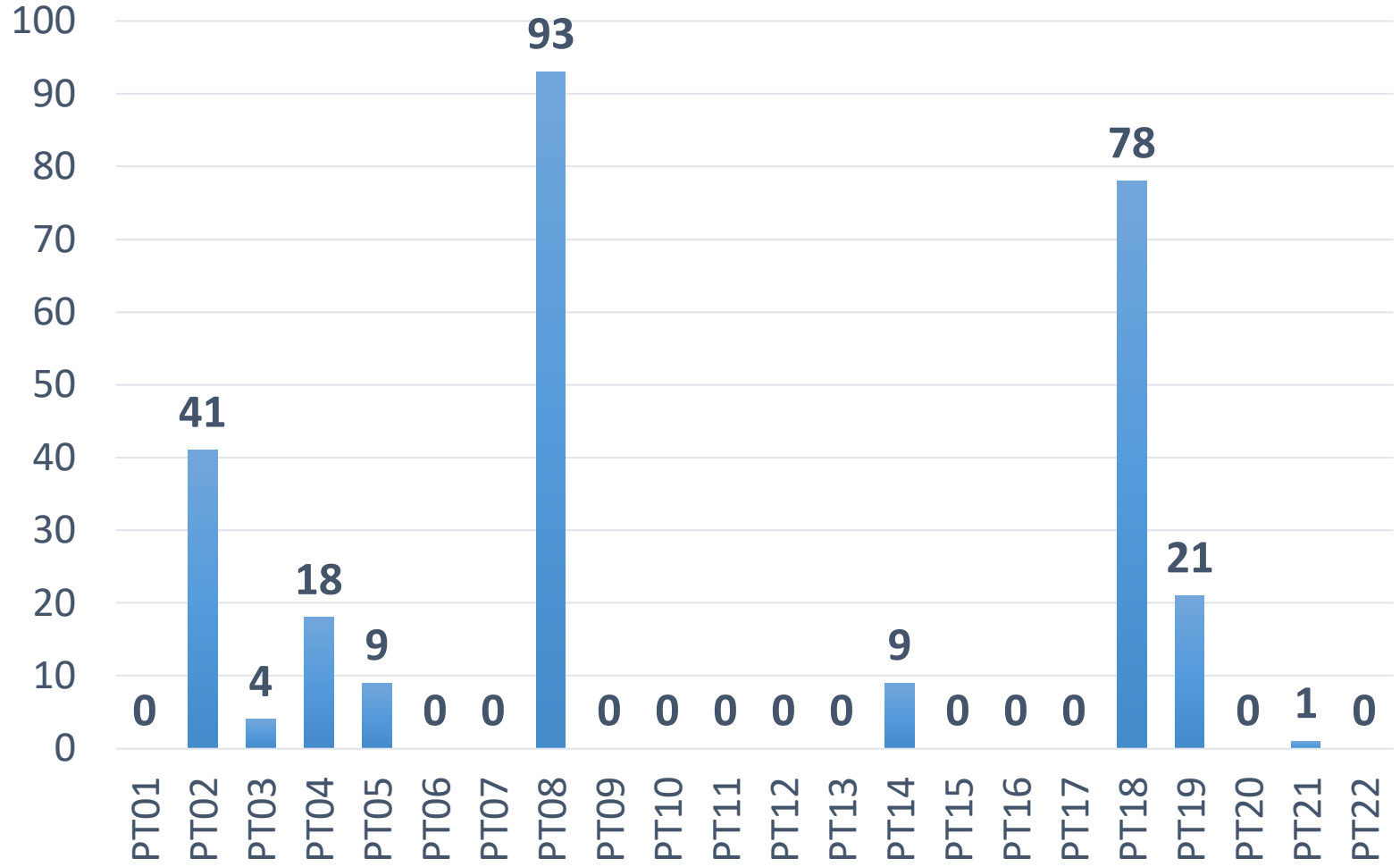
(Tipologia di prodotti dal 31/10/2022 al 31/10/2023)



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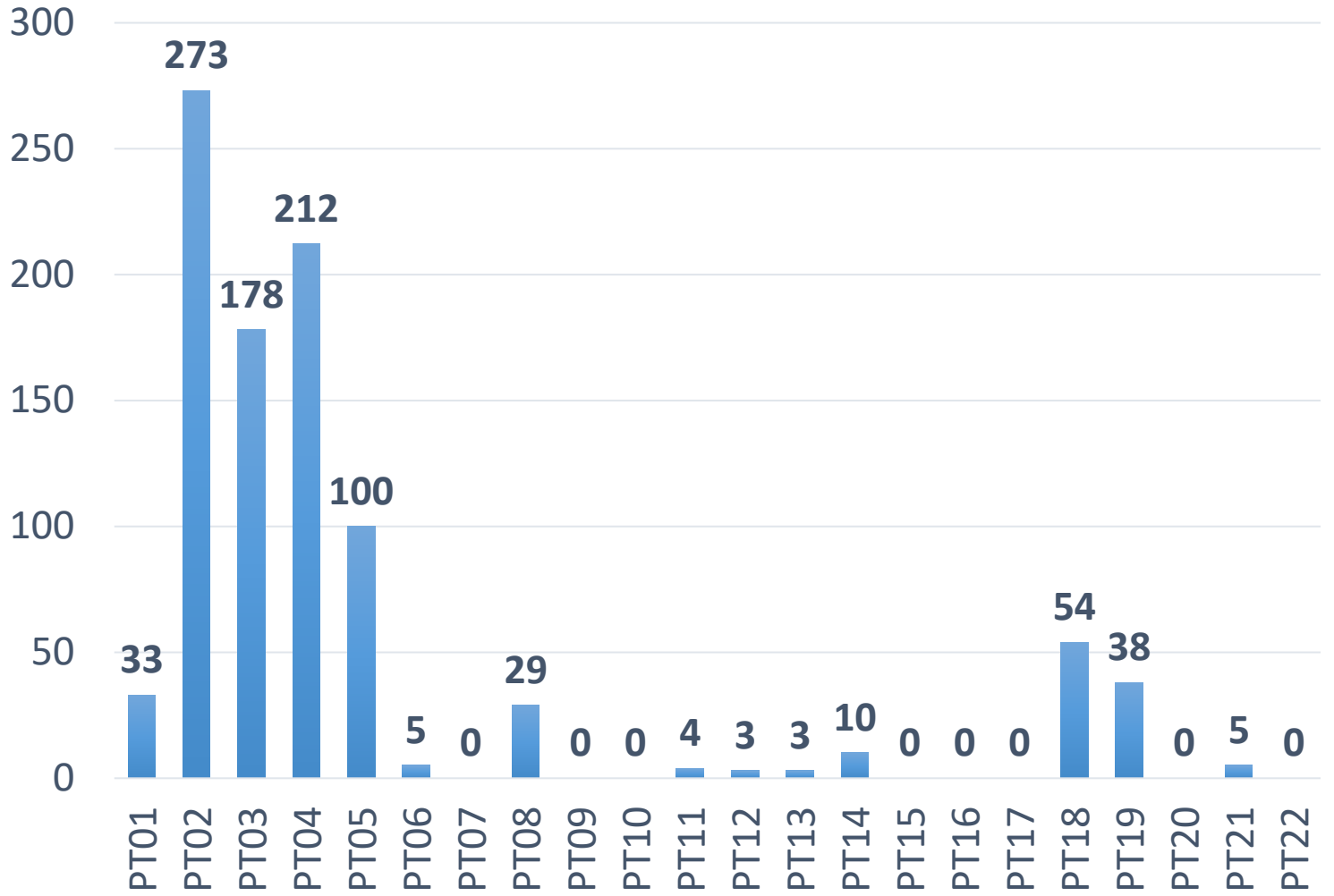

R4BP 3

RACCOMANDAZIONI

IL GRUPPO DI COORDINAMENTO (CG)

Articolo 35

Comunicazione delle obiezioni al gruppo di coordinamento

1. È istituito un gruppo di coordinamento per esaminare qualsiasi questione, diversa da quelle di cui all'articolo 37, intesa a stabilire se un biocida per il quale è stata presentata una domanda di riconoscimento reciproco conformemente all'articolo 33 o all'articolo 34 soddisfi le condizioni per il rilascio dell'autorizzazione di cui all'articolo 19.

Tutti gli Stati membri e la Commissione hanno il diritto di partecipare ai lavori del gruppo di coordinamento. L'Agenzia svolge le funzioni di segretariato del gruppo di coordinamento.

RACCOMANDAZIONI
ACCORDI GENERALI CG

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Nome	Dimensioni	Data di modifica	Azioni
CG-57-2023-10 AP 6.1 Application of referral agreements_vf_rev.pdf	56.28 KB	3 luglio 2023 15:10	
CG-57-2023-05 AP 14.3 BPF Art 19(5).pdf	145.35 KB	3 luglio 2023 12:58	
CG-56-2023-30 AP 14.1 Post-authorisation conditions for NA and SA_final.pdf	138.79 KB	3 maggio 2023 11:08	
CG-55_e-c Concentration, contact time for various groups of target organisms_vf.pdf	204.38 KB	10 marzo 2023 15:49	
CG-55_e-c PT8 outdoor treatment of wood UC1-2_final.pdf	744.37 KB	8 marzo 2023 16:51	
CG-55_e-c Revised harmonised SPC sentences for AVK PT14 products_final.pdf	1.58 MB	3 marzo 2023 08:28	
CG-54-2022-07 AP 14.1 Classification of products containing H2O2_Final.pdf	179.48 KB	8 dicembre 2022 16:30	
CG-54_e-c Use of the term as required for the application frequency_vf.pdf	663.9 KB	1 dicembre 2022 07:28	
CG-53-2022-07 AP 14.1 Shelf-life setting during PA_vf.docx	432.16 KB	26 settembre 2022 09:21	
CG-52_e-c Impact v4 PT19 EFF guidance_public_final.pdf	270.3 KB	12 settembre 2022 09:13	
CG-52-2022-14 AP 7.2 Mutual Recognition of a mutual recognition_vf.pdf	156.9 KB	22 luglio 2022 09:47	
CG-51_e-c Guidance for first aid instructions_vf.pdf	316.86 KB	7 giugno 2022 15:50	
CG-51_e-c AVK PT14 RNL waiving justifications for physical hazards_vf.pdf	239.27 KB	7 giugno 2022 11:51	
CG-51_e-c Inclusion of P-statements in SPC_Final.pdf	148.8 KB	17 maggio 2022 17:06	
CG-50_e-c Thermally inactivated target organisms_vf.pdf	192.52 KB	11 aprile 2022 10:23	
CG-50-2022-05 AP 16.6 ED assessment of co-formulants by applicants_vf.pdf	222.27 KB	24 febbraio 2022 08:21	
CG-50-2022-07 AP 16.2 Dermal absorption value in PAs_vf.pdf	179.12 KB	24 febbraio 2022 07:51	
CG-49_e-c_RMMs for PT18 products_vf.pdf	917.48 KB	17 gennaio 2022 08:01	
CG-49-2021-07 AP 14.2 Significant indication of ED_vf.pdf	112.14 KB	15 dicembre 2021 15:12	
CG-46_e-c_RMM PPE Oak processionary caterpillar_Final.pdf	694.57 KB	15 giugno 2021 09:44	
CG-46-2021-27 Date of appl ENV TAB.pdf	483.64 KB	15 giugno 2021 08:11	
CG-45_e-c Compliance with Annex H of EN 599_vf.pdf	175.59 KB	17 maggio 2021 07:23	

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ACCORDI GENERALI CG

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Post-authorisation conditions for national and simplified product authorisation: harmonising practices	
Date of agreement: 26 April 2023	Classification: **Public**

1. Introduction

Post-authorisation conditions should always remain **an exception** and may only be considered case by case. The purpose of this document is to define on what grounds a post-authorisation condition could be justified for biocidal product (BP) and biocidal product family (BPF) authorisation applications to harmonise the practices. It is expected that such harmonised practices will prevent the submission of referrals to the CG.

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In order to support harmonisation of the decision-making process by MSs, the following criteria are proposed in order to consider whether a post-authorisation condition may be acceptable:

- The data available in the application enabled the MS to conclude on the risk assessment and the efficacy assessment (i.e., no data gap preventing them to conclude),
- The data to be provided post-authorisation is not affecting the classification and labelling of the BP/BPF or the efficacy/risk assessment.

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Post-authorisation conditions for national and simplified product authorisation: harmonising practices	
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By applying these criteria, a post-authorisation condition for BP/BPF authorisation must never be set in the situations listed below:

- For NA of BP/BPF: physical, chemical, physico-chemical data and physical hazards and respective characteristics that affect product classification and labelling, or physical, chemical, and technical properties that would affect Article 19(1)[2] conditions and/or the efficacy/risk assessment.
- For SA of BP/BPF: physical, chemical, physico-chemical data and physical hazards and respective characteristics that affect product classification and labelling, or physical, chemical, and technical properties that would affect Article 25 conditions and/or the efficacy assessment.
- Complete long-term stability study is missing when authorisation is granted for the BP/BPF in an NA or SA procedure[3] for which the application was submitted after the publication of this CG document, the revised BPC document and the revised APCP TAB entry document concerning shelf-life.

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DISCLAIMER: This document was agreed by the Coordination Group at the CG-53 meeting.

Shelf-life setting during the authorisation of biocidal products	
Date of agreement: 22 September 2022	Classification: **PUBLIC**

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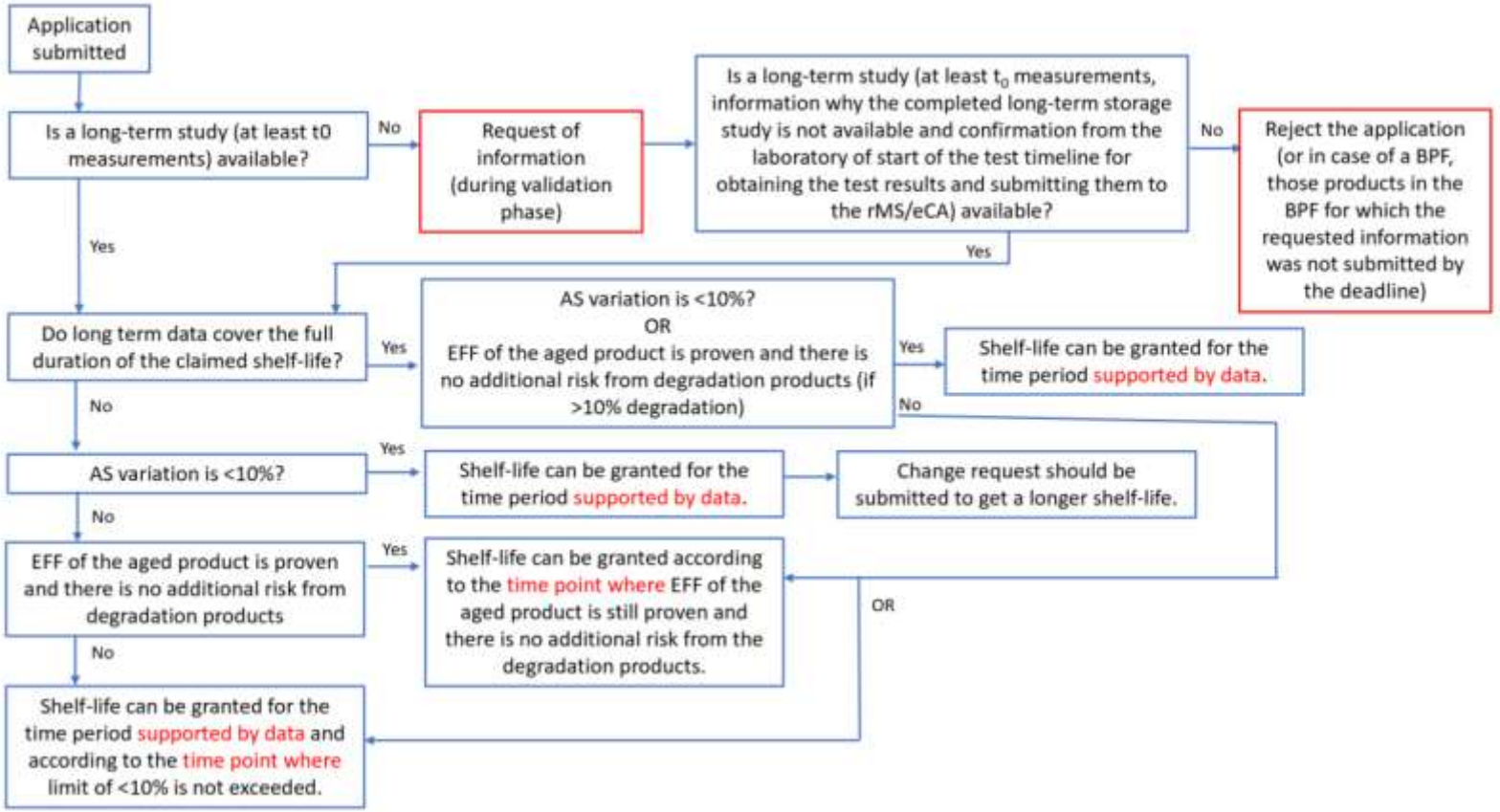
Shelf-life setting during the authorisation of biocidal products	
Date of agreement: 22 September 2022	Classification: **PUBLIC**

In case of NA and UA procedures:



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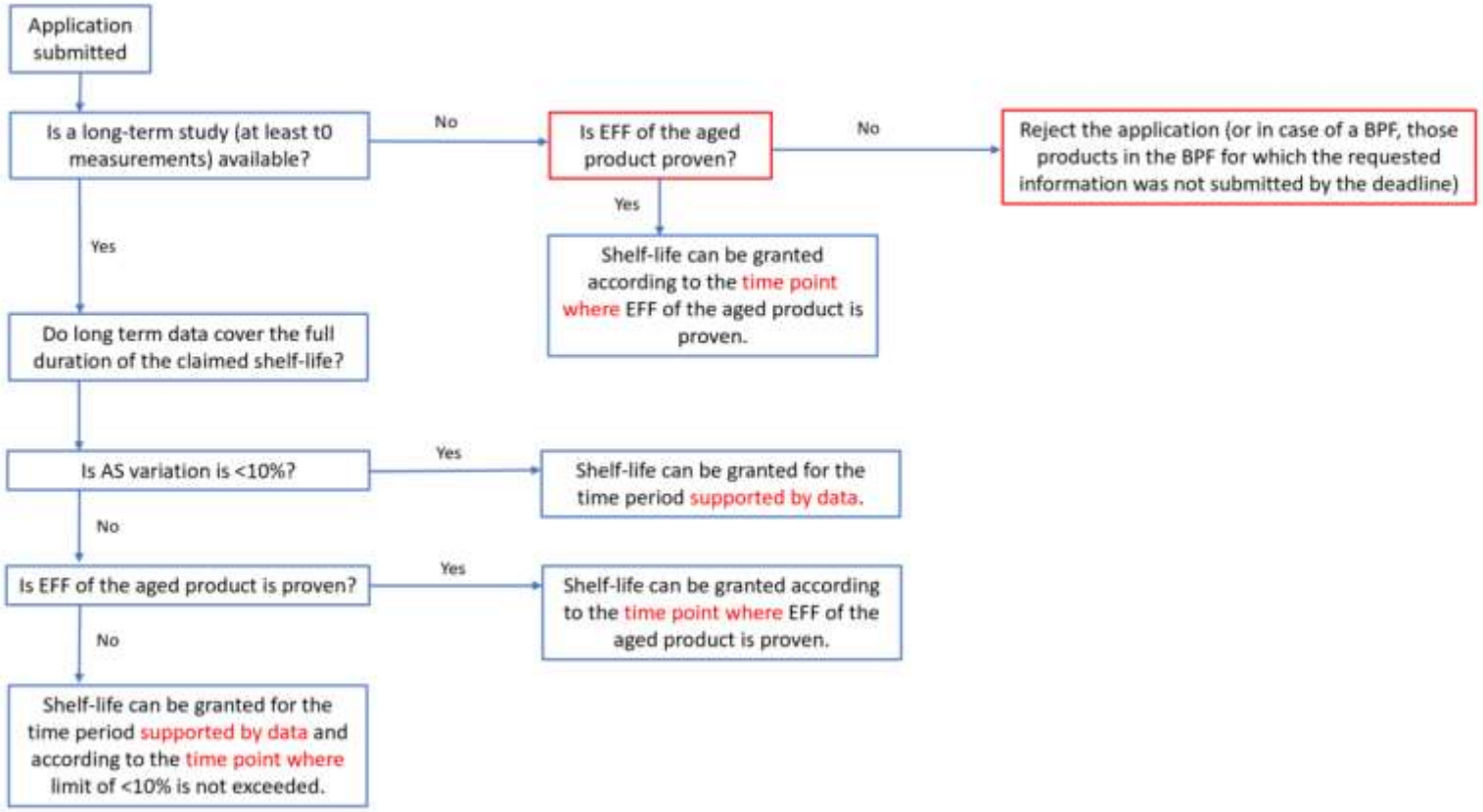
Shelf-life setting during the authorisation of biocidal products	
Date of agreement: 22 September 2022	Classification: **PUBLIC**

In case of SA procedures:



Grazie per l’attenzione