

12[™] PLENARY MEETING OF THE BPR SUBGROUP OF THE FORUM FOR EXCHANGE OF INFORMATION ON ENFORCEMENT

BPRS-12

23 MARCH 2021

REMOTE MEETING

CONTENTS

- I. SUMMARY RECORD OF THE PROCEEDINGS
- II. CONCLUSIONS AND ACTION POINTS
- III. LIST OF ATTENDEES
- IV. ANNEXES



Glossary of acronyms and abbreviations

| AOB | Any Other Business |
|----------|--|
| ASO | Accredited Stakeholder Organisation |
| BEF-1 | First Biocides Enforcement Project |
| BPRS | BPR Subgroup of the Forum which coordinates the BPR enforcement |
| BPC | ECHA Biocidal Product Committee |
| CLP | Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures |
| COM | European Commission |
| DG | Directorate General at the Commission |
| DG SANTE | Directorate General on Health and Food Safety/European Commission |
| DG GROW | Directorate General for Internal Market, Industry, Entrepreneurship and SMEs |
| EU | European Union |
| FORUM | The Forum for Exchange of Information on Enforcement: Network of authorities responsible for the enforcement of the REACH, CLP, PIC and BPR regulations in the EU, Norway, Iceland and Liechtenstein |
| HET | ECHA Harmonised Enforcement Team (former ECHA Forum Secretariat) |
| ICSMS | Internet-supported information and communication system for the pan- European market surveillance |
| MAWP | Multiannual Work Programme |
| MFF | ECHA Multi annual financial framework |
| MOC | Manual of Conclusions |
| MS | Member State |
| MSR | Market surveillance Regulation |
| NC | National Coordinator of the Enforcement Project |
| NEA | National Enforcement Authority |
| RAPEX | Rapid Alert System |
| REACH | Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals |
| REF | REACH-EN-FORCE, Harmonised Enforcement Project of the Forum |
| ROPs | Rules of Procedure |
| SPC | Summary of Product Characteristics |
| TA | Treated Articles |
| TF | Task Force of the Forum/BPRS |
| TfT | WG of the Forum/BPRS on Training for Trainers for national inspectors |
| WG | Working Group of the Forum/BPRS |
| WIN PPIE | ECHA Work Instruction - Processing Practical Issues for Enforcement |



I. Summary record of the proceedings

Item 1 - Welcome and introduction

The Chair of the BPRS opened the plenary meeting which, for the third time, was held remotely.

The Chair informed the plenary that the meeting was recorded for the purpose of writing the minutes, and that the recordings are going to be destroyed after the minutes are adopted. The final agenda was adopted (see Annex I), and two AOBs were included, i.e. 'The Netherland case study on monitoring biocide market', and 'Austrian analysis on face mask and biocides'. Four room documents were circulated to the BPRS members. No conflicts of interest (according to Article 9(2) of the Forum Rules of Procedure - ROPs) were declared at the meeting.

The ECHA Harmonised Enforcement Team (HET) informed the members that all action points from the BPRS-11 were discharged. The item related to the cooperation between BPRS and BPC on risk management measures is going to be tackled under item four of the BPRS-12.

Item 2 – Update on Forum Work Programme 2021

2.1 Updates on the Forum plans following Management Board decision of December 2020

A member of the HET updated the plenary on the discussion that was held at the ECHA Management Board n. 60 in December 2020 on the ECHA work programme 2021. The Management Board outlined the general prioritisation activities that will require some reductions in term of resources in different functions of the Agency. Those reductions will also affect the work of the HET, and therefore, to some extent, the Forum and BPRS work. In this light, a document reporting future actions to be taken by the HET impacting the way of working of the two groups was circulated among the Forum and BPRS members. At the BPRS-12 (and Forum-37), the concerned document was discussed among the BPRS members with a final agreement to test this during meetings in 2021.

2.2 Implementation of Interact Portal BPR and future plans

The WG performed testing of the test version of Interact BPR. The version released at the end of 2020 was not fit for being released to national inspectors. The BPRS was informed that due to budgetary constraints that affect ECHA's IT developments, further development of the Interact BPR was postponed. No exact timeline for the continuation of the development of the tool is currently set. The BPRS will be duly informed when more information becomes available.

In this light, the BPRS agreed to set the WG as 'inactive' until the testing can continue. Therefore, there will be no further reporting of the WG activities to the BPRS until the testing resumes.

The BPRS was also informed on some updates related to Interact Portal. Specifically, as of the BPRS-12, all invited experts are going to get access (by default) to the 'Meetings module' and related documents (unless otherwise indicated by the BPRS members).

Ultimately, the BPRS members were reminded about the on-going survey on the 'Collaboration module', and the information about the up-coming consultation on Audit Guidelines.

Item 3 - Practical issues for enforcement



Issue BPRS 9.1 - Borderline issue

The practical issue focuses on what constitutes a 'biocidal product', with emphasis on the element of 'intent' as defined by the existence of a biocidal claim in the label and/or marketing material. Last December 2020, the written adoption of the issue was stopped by a negative vote submitted by a BPRS member. Afterwards, bilateral discussions took place among the concerned BPRS member, the HET and the ECHA Legal Affair Unit, leading to a sixth written consultation of the revised issue.

At the BPRS-12, the members discussed again the new draft conclusion, and the HET was tasked to include in the text some further inputs expressed by two BPRS members. A seventh written consultation and a possibly adoption to follow in due time.

Issue BPRS 10.1 - Enforcement of biocidal products with unstable active substances

The issue focuses on the conformity of biocidal products when the concentration of the active substances indicated on their labels is different than the concentration measured by the enforcement authority, without showing a decrease of the efficacy of the biocidal functions. The BPRS highlighted that regulatory consequences may appear on the different ways of reporting active substances concentration present in biocidal products, i.e. between the measured 'pure' concentration (perform by the enforcement bodies), and the concentration indicated on the label/SPC - 'technical' concentration.

Based on the previous discussion that took place at the BPRS-11, the ECHA Biocides Assessment Unit was consulted and the issue was tabled at the ECHA Coordination Group (CG) meeting in February 2021. At the BPRS-12, the feedback from the ECHA Coordination Group was shared with the BPRS members, and the HET was tasked to collect in writing the BPRS members' comments. The HET, together with the originator of the issue and the ECHA Legal Affair Unit were tasked to draft a legally sound conclusion of the Issue and to consult the BPRS members accordingly.

Item 4 - Cooperation with ECHA bodies / Secretariat

4.1 Update from Forum-37

The Forum Chair debriefed the BPRS members on the key issues tackled during the last plenary of the Forum (i.e. Forum-37). Specifically, the group agreed on the scope of the REF-10 project, which will be focused on REACH/POP Restrictions, and REACH Substance in Article (i.e. Article 33 obligations). An extended scope on 'Restriction of Hazardous Substances in Electrical & Electronic Equipment' (RoHS) and Toys Directives was also endorsed.

The Forum members extended the REF-10 national coordinator training to also include the training for national inspectors for the year 2021. The merging of the two events will aim at improving the use of resources within the HET and Forum members.

Moreover, the Forum members also agreed that the BPRS should only focuses on BPR aspects leaving horizontal matters and cross-legislation issues on the Forum's remit. This agreement was conditional to the BPRS endorsement that was taken under the agenda item 2.1 of the BPRS-12.

Other aspects reported to the plenary by the Forum Chair concerned the inputs related to enforcement practices that the Forum will provide in view of the forthcoming REACH review, and an update on the cooperation between the Forum and ADCOs - EUPCN.

4.2 Debriefing from the meeting with ECHA Directors and Forum/BPRS Chairs



The Chair informed the BPRS members on the discussions that took place during the remote meeting with the ECHA Directors held on 18 March 2021. Among the topics tackled during the meeting, the Chair shared with the BPRS members an update on the ECHA planning in view of the future Chemical Strategy for Sustainability (CSS) and the potential involvement of Forum and BPRS. More information on this topic will be provided at the BPRS-13.

4.3 Cooperation with the Biocidal Product Committee

The BPC Chair updated the plenary on the *ad hoc* BPRS consultation concerning RMMs for wood preservatives that took place in March 2021.

The BPC Chair will take the BPRS feedbacks to the next European Commission Standing Committee meeting for biocides, where a draft Commission decision on the approval might be tabled and followed by a written procedure for adoption. An update from the BPC Chair on the *ad hoc* collaboration with the BPRS will take place at the BPRS-13.

Finally, some BPRS members suggested the BPC Chair provide more detailed information in view of future collaboration. This will help the BPRS members in accurately analysing the situation and expressing valuable opinions.

Item 5 - BPRS enforcement activities

BEF-2

The BPRS agreed with the scope of BEF-2 project as proposed by the WG members. Specifically, the second harmonised enforcement project to be run under the umbrella of the BPRS will be focused on biocidal products with approved/non-approved active substances either authorised under the BPR or available on the market under national transitional measures. Several modules will be integrated in the questionnaires for inspections, namely on Article 95 obligations, labelling requirements, (online) advertising, identification via chemical analysis of declared (/hidden) active substances (/related efficacy concentration), and disinfectant products.

In the next months of activities, the WG will be elaborating the BEF-2 draft Manual and questionnaire for inspections. The BPRS members will be asked to contribute to the work via written consultations.

The BPRS members were invited to nominate the National Coordinators for the BEF-2 by end of May.

The BPRS agreed to extend the mandate of the Working Group BEF-2 and to task it with preparation of next Training for Trainers 2021, which will be indeed focused on the scope of the BEF-2 project. The event to be delivered around Q4 2021 will also cover the National Coordinators training.

The BPRS members were invited to appoint new experts to join the WG BEF-2, especially for the elaboration of the materials for training for trainers 2021.

BEF-1

The WG members finalised the BEF-1 Practical guide for inspectors (so-called *Tips&Hints*) by integrating the comments received from the BPRS members and National Coordinators of the BEF-1. The document will be soon adopted via written procedure, and it will serve as guide for future enforcement activities on treated articles.



The WG Chair invited the BPRS members to attend the *ad hoc* workshop focused on the results of the BEF-1 that will be held remotely on 26 April. The event will create an opportunity for the ECHA Accredited Stakeholders (ASOs) to discuss and analyse the key aspects of the BEF-1 with the experts of the WG, and it aims at raising awareness on the obligations of the BPR.

REF-8 (BPR module)

The Chair updated the BPRS on the progress report of the WG. The reporting phase for REF-8 National Coordinators is still on-going with a deadline set on 31 March. Preliminary results of the project will be presented at the next plenary meeting in June. The adoption and publication of the REF-8 report is expected by the end of 2021.

Item 6 - Updates on relevant developments by the European Commission

6.1 General updates on the BPR provisions by the European Commission

The DG SANTE representative gave an update of the COM's activities that were relevant for the work of the BPRS. The presentation started with the report of the actions related to COVID-19 and its impact on biocides. Specifically, the speaker informed the members that Member States continued granting Article 55(1) derogations for disinfectants during the last months, i.e. approximately 200 notifications since November 2020. Moreover, two decisions were issued on the extension for 550 days of the emergency permit for isopropanol-containing disinfectants.

The speaker informed the BPRS on the discussion on RMMs for biocidal products and treated articles. In particular, Competent Authorities for biocides are currently questioning the possibilities for Member States to set RMMs for treated articles already at product authorisation stage. That could for instance foresee the inclusion in treated articles labels of certain sections of the SPC of the biocidal products used for treating articles. In this regard, the COM was invited to consider whether it is willing to involve the BPRS in future consultation on the matter. Moreover, the COM was also tasked to investigate whether there is the possibility to extend the guidance on biocidal product efficacy to cover also treated articles. A follow-up discussion will take place at the BPRS-13.

Regarding the status of the renewal for anticoagulant rodenticides, the COM representative mentioned that a second renewal of product authorisations for anticoagulant PT 14 products is approaching, with first submissions of applications expected in June 2021, and that a potential harmonised approach by Member States is still being discussed with the competent authorities .

The presentation from DG SANTE also touched upon the on-going discussion at COM level on the impact of hazardous biocidal products to bees, regarding the need to further develop guidance documents aiming at assessing the risk to bees for the use of biocidal products and the introduction of warning statements for biocidal products potentially hazardous to bees.

Other updates were related to: i) the technical assistance from COM to Member States in the framework of the evaluation of active substances in plant protection products and biocidal products for the years 2022-2027; ii) the Regulation on explosive precursors and the implications for certain biocidal products; iii) the evaluation of MRLs interim approach; iv) the authorisation procedures related to the UK's withdrawal from the EU; v) and the latest version of the Art 65(3) reporting template.



6.2 Updates from DG GROW Working Group on Borderline between BPR and Cosmetic Regulation

A representative of DG GROW updated the plenary on the WG activities on borderline issues between the BPR and the Cosmetic Products Regulation. Specifically, the speaker reported that the working document on 'not-admissible claims on hydroalcoholic hand gels placed on the market as cosmetics' was duly translated in all EU languages and it is now available on Commission website.¹

The COM representative suggested NEAs to circulate the concerned document on borderline issues to the general public, if needed.

Item 7 - Activities in Member States and cooperation with other networks

7.1 Update from ADCO Chairs meeting

The Chair informed the plenary on the collaboration between the BPRS and the ADCO in the framework of "peer review" partnership. Details on the organisation and future activities will be shared over the next months. The Chair also updated the BPRS on the potential collaborations that might take place between the BPRS and the EU Product Compliance Network (PCN). A follow-up discussion will take place at the BPRS-13 in order to clarify the nature and intensity of these tasks.

7.2 NL Case study on European Court decisions for biocides

The Dutch BPRS member delivered a presentation focused on the recent European Court decisions concerning biocides. The initial discussion on this topic was triggered at the BPRS-9 when the BPRS members initially tackled the Practical issue BPRS-9.1 on biocides borderline issues. The speaker aimed with the presentation at supplementing some legal information reported in the Issue. Essentially, the Dutch BPRS member started with the interpretation of the concept of 'biocidal products' as defined in Article 3 of the BPR and touched upon the analysis of cleaning agents which include bacteria, enzymes or other constituents that do not directly have an impact on harmful organisms, for which they are intended, but on the creation or maintenance of a possible living environment targeting harmful organisms. A follow-up discussion took place among the BPRS members on what requirements should be imposed for such biocidal products and how this would influence the market (and related enforcement). The BPRS members were then invited to liaises with the NL member to further evaluate the case at hand. If needed, a follow-up discussion will be tabled at the BPRS-13.

7.3 SE paper on the efficacy of treated articles

The Swedish BPRS member presented to the plenary a national document concerning the concept of efficacy for treated articles. Currently, no guidance was developed from COM and ECHA's side on how to assess the efficacy for insecticide and repellent treated articles that are considered biocidal products. This document aims at clarifying these requirements providing some information concerning the health and the environmental risks associated with these products, and the related recommendations on how to label them in order to minimise those risks. Moreover, the document also reports information about suitable tests to assess efficacy for treated articles, and some results of internet search showing the diversity of such products available on the EU market (ranging from clothing to products

¹ Working document on `not-admissible claims on hydroalcoholic hand gels placed on the market as cosmetics' available at: https://ec.europa.eu/growth/sectors/cosmetics/products/borderline-products en



for animals). The Swedish BPRS member was tasked to collect written comments from the BPRS members and tabled them at the BPRS-13 for continuing the concerned analysis.

Item 8 - AOBs

8.1 Future BPRS plenaries dates

The tentative dates for the BPRS meetings in 2021 are the following: i) BPRS 13: 22-23 June 2021; ii) BPRS-14: 16-18 November 2021.

8.2 NL case study on Monitoring

The Dutch BPRS alternate presented to the BPRS members a case study focused on the difficulties in monitoring the EU market concerning biocides. The speaker reported that due to the large volumes of biocides sold in the Netherlands, it appears very difficult to keep track of the exact amount of chemicals circulating every year on the market. This is even more evident nowadays due to the increase of disinfectant products caused by the COVID-19 pandemic.

The speaker presented a potential system which might lead authorisation holders, and more in general industries involved in the biocides world, to annually report the exact quantities of active substances/biocidal products placed on the market.

The speaker also clarified that, under Article 68(1) of the BPR, authorisation holders are already obliged to keep records of these information, though the data must cover a period of at least ten years and must be submitted only upon governments' requests (moreover, an *ad hoc* guidance for NEA on how to enforce Article 68 is still missing).

The Dutch BPRS alternate was tasked to collect written comments from the BPRS members and table them at the BPRS-13 for continuing the discussion.

8.3 AT case study on face mask

The Austrian BPRS member presented a case study arising from the recent marketing of PPE face masks with a claim for sterilisation with ethylene oxide. The BPRS were asked to share their experiences in enforcing such products.

The Austrian BPRS member will collect in writing BPRS opinions on the issue, and the HET will table a follow-up discussion at the BPRS-13, if needed.



II. Conclusions & action points adopted at the BPRS-12 (public)

| Agenda point | Conclusions / decisions / minority opinions | Action requested after the meeting |
|--|---|--|
| Item 1- Welcome and intro | | |
| 1.2 Adoption of the | BPRS adopted the | |
| Agenda | agenda. | |
| Item 2 - Update on Foru | n Work Programm | e 2021 |
| 2.1 Updates on the Forum plans following Management Board decision of December 2020 | BPRS agreed with the proposal to further focus the BPRS plenaries on the BPR. | HET will distribute the final version of the document adopted with visible changes to both BPRS and the Forum by 26 March |
| 2.2 Implementation of Interact Portal BPR and future plans | | |
| 2.2.1 Progress report and mandate amendment | The BPRS revised the mandate of the WG. | |
| Item 3 - Practical issues | for enforcement | |
| Practical issue B-9.1 on biocide borderline issues | | DE BPRS member will propose written changes to the text by 2 April |
| | | HET will launch a written consultation of the revised issue with the BPRS by 9 April |
| | | After consideration the BPRS comments HET will launch written procedure for adoption of the practical issue. |
| Practical issue B-10.1 on concentration of unstable active substances in biocidal products | | BPRS members are invited to send written feedback on the proposal by the FR BPRS member as well as the response from the CG by 2 April |
| | | HET will draft a conclusion for the practical issue and send for written consultation by 16 April |
| Item 4 – Cooperation wit | h ECHA bodies / S | ecretariat |
| 4.1 Update from Forum- 37 | | |
| 4.2 Debriefing from ECHA Directors and Forum/BPRS Chairs | | |



| A manufacturation | 0 | A ation was an all after the |
|----------------------------|----------------------------------|------------------------------------|
| Agenda point | Conclusions / decisions / | Action requested after the |
| | _ | meeting |
| 4.2 Cooperation with the | minority opinions BPRS noted the | |
| 4.3 Cooperation with the | relevance of | |
| Biocidal Product | feedback on | |
| Committee | enforceability in the | |
| | substance approval | |
| | process and offered | |
| | to provide ad hoc | |
| | consultations of risk | |
| | management | |
| | measures to the | |
| | BPC in the future. | |
| Item 5 - BPRS enforceme | ent activities | |
| 5.1 BEF-2 | | |
| 5.1.1 Scope of the project | The BPRS has | BPRS members are invited to |
| | agreed to the scope | nominate national coordinators |
| | of BEF-2 project as | for the BEF-2 by end of May |
| | proposed by the | |
| | WG. | |
| 5.1.2 Merging with the | The BPRS agreed to | BPRS members are invited to |
| Training for Trainers 2021 | extend the mandate | appoint experts to join the WG |
| | of the Working | BEF-2 especially for the |
| | Group BEF-2 and | elaboration of the materials for |
| | task it with | training for trainers 2021 by 16 |
| | preparation of | April |
| | Training for Trainers 2021 | |
| | focusing on the | |
| | same subject as | |
| | BEF-2 project. | |
| 5.1.3 Mandate | BPRS revised the | |
| amendment | mandate | |
| 5.2 On-going Working | | |
| | | |
| Groups BEF-1 | The BPRS revised | BPRS members and National |
| DLL-1 | the mandate. | Coordinators are invited to |
| | the manuate. | participate to the ASOs |
| | | workshop and express their |
| | | interest by 10 April to the HET |
| | | micerese by 10 April to the HET |
| | | HET will send the final BEF-1 Tips |
| | | & Hints for adoption in written |
| | | procedure after the BPRS-12. |
| REF-8 | The BPRS revised | |
| | the mandate. | |
| Item 6 Updates on devel | opments by Comm | ission |
| 6.1 Updates from DG | | The COM is invited to provide the |
| SANTE on the BPR | | latest version of the Art 65(3) |
| provisions | | reporting template to the HET by |
| F | | 2 April |
| | | |



| Agenda point | Conclusions / decisions / minority opinions | Action requested after the meeting |
|---|--|---|
| | The second secon | HET will distribute it to the BPRS members. |
| | | COM is invited to consider whether it is willing to consult the BPRS regarding any discussion regarding the labelling of treated articles and come back at BPRS-13. |
| | | COM is invited to consider whether guidance on efficacy can be extended to also cover the treated articles and come back at BPRS-13. |
| 6.2 Updates from DG GROW Working Group on Borderline between BPR | | |
| and Cosmetic Regulation | Ct-t d | a a santi a sa a saithle a tha a sa |
| Item 7 Activities in Mem networks | er States and coo | peration with other |
| 7.1 Update from ADCO Chairs meeting and European Product Compliance network | | |
| 7.2 NL Case study on European Court decisions for biocides | | |
| 7.3 SE paper on the efficacy of treated articles | | BPRS members are invited to send questions on the document to the SE BPRS member. |
| Item 8 AOBs | | |
| 8.1 Dates of next BPRS plenary meetings | The indicative dates for next BPRS meetings are: | |
| | - BPRS 13: 22-24 June 2021 - BPRS-14: 16-18 November 2021 | |
| 8.2 NL case study on monitoring volumes of biocides | | BPRS members are invited to send responses to questions raised by the NL BPRS alternate member and copy the HET by end of April. |
| | | NL alternate BPRS member will consider reporting back on the |



| Agenda point | Conclusions / decisions / minority opinions | Action requested after the meeting |
|---|---|--|
| | | BPRS feedback received at BPRS-13 |
| 8.3 AT case study on face mask sterilised with ethylene oxide | | BPRS members are invited to send responses to questions raised by the AT BPRS member and copy the HET by end of April. AT BPRS member will report back on the BPRS feedback received at BPRS-13 |
| Item 9 - Adoption of conclusions and action points | | |



III. List of attendees of the BPRS-12

BPRS members

| | Country | Name |
|----|---------|------------------------------|
| 1 | AT | ANWANDER Eugen |
| 2 | BE | DE VOS Helmut |
| 3 | CH | BUERGY Heribert |
| 4 | CY | ELIA Nikos |
| 5 | CZ | JAROLIM Oldrich |
| 6 | DE | SCHROETER Meike |
| 7 | DK | HANSEN Lise Bach |
| 8 | EE | LINNO Annemari |
| 9 | EL | GKILPATHI Dimitra |
| 10 | ES | ORTEGA Isabel |
| 11 | FI | MÄKI Markus |
| 12 | FR | VERDIER Elodie |
| 13 | HR | PILETIC Kaca |
| 14 | HU | NEMET Balazs |
| 15 | IE | CANTY Mary |
| 16 | IS | INGVARSDOTTIR Hafdis Inga |
| 17 | IT | RAVAIOLI Francesca |
| 18 | LI | RELLA-QUADERER Maria-Rosaria |
| 19 | LT | HAKAITE Palmira |
| 20 | LU | HERMES Joe |
| 21 | LV | DAUGELE Santa |
| 22 | MT | GARG Ramandeep |
| 23 | NL | BRAAM Marianne |
| 24 | NO | SKARGARD Cathrine |
| 25 | PL | WASIK Romualda |
| 26 | PT | DIAS Marina |
| 27 | RO | CIRLAN Cristiana |
| 28 | SE | KARLSSON Jenny |
| 29 | SI | HAJRLAHOVIC-MEHIC Semira |
| 30 | SK | POCAROVSKA Miriam |

Invited Experts/Forum members

| | | Country | Name |
|---|---|---------|----------------|
| ĺ | 1 | DE | VOM HOFE Katja |

Advisers

| | Country | Name |
|---|---------|------------------|
| 1 | DE | FRENZEL Stefan |
| 2 | DE | WURSHORN Sibylle |



| | Country | Name |
|---|---------|-----------------------|
| 3 | DK | MADSEN Betina |
| 4 | EL | PAPATHANASIS Thanasis |
| 5 | FI | OLLIKKA Jussi |
| 6 | FR | ENSLEN Niels |
| 7 | NL | DE Boer Jabik |

European Commission representatives

| | Country | Name |
|---|----------|------------------|
| 1 | DG SANTE | NEGULICI Ligia |
| 2 | DG GROW | SCAZZOLA Roberto |

ECHA staff

| | ЕСНА | Unit |
|---|-------------------------|---|
| 1 | ANNYS Erwin | Head of Unit Support and Enforcement |
| 2 | BARANSKI Maciej | Support and Enforcement |
| 3 | CALVO TOLEDO Juan Pablo | Support and Enforcement |
| 4 | FRONTINI Ales | Support and Enforcement |
| 5 | NIKULA Terhi | Support and Enforcement |
| 6 | TECCE Nicola | Support and Enforcement |
| 7 | TLOCZEK Magdalena | Support and Enforcement |
| 8 | TUOMAINEN Anita | Support and Enforcement |
| 9 | VAN DE PLASSCHE Erik | BPC Committee Chair |



IV. List of Annexes

Annex 1. Adopted agenda of BPRS-12

Annex 2. List of mandates of Forum / BPRS WGs adopted at the BPRS-12

- 2 a. BPRS WG BEF-1
- 2 b. BPRS WG Training for Trainers 2020
- 2 c. BPRS WG Interact BPR
- 2 d. Forum/BPRS WG REF-8
- 2 e. Forum/BPRS WG MSs Reporting
- **2 f.** BPRS WG BEF-2
- **2 g.** BPRS WG Training for Trainers 2021
- **2 h.** Forum REF Prioritisation



Annex 1: Agenda of the 12th meeting of the BPR Subgroup of the Forum

Item 1 - Welcome and introduction

10:30-10:45

- 1.1 Opening by the BPRS Chair
- 1.2 Adoption of the agenda and declarations of conflict of interest
- 1.3 Action points and written procedures from BPRS-11

Item 2 – Update on Forum Work Programme 2021

10:45-12:10

- 2.1 Updates on the Forum plans following Management Board decision of December 2020 (45')
- 2.2 Implementation of Interact Portal BPR and future plans (30')
 - 2.2.1 Progress report and mandate amendment

Item 3 - Practical issues for enforcement

12:10-12:50

3.1 Items raised by the BPRS/ECHA/COM (list of practical issues is prepared independently from the agenda)

Item 4 - Cooperation with ECHA bodies / Secretariat

13:35-14:15

- 4.1 Update from Forum-37 (10')
- 4.2 Debriefing from ECHA Directors and Forum/BPRS Chairs (10')
- 4.3 Cooperation with the Biocidal Product Committee (20')

Item 5 – BPRS enforcement activities

14:15-15:00

- 5.1 BEF-2 (25')
 - 5.1.1 Scope of the project
 - 5.1.2 Merging with the Training for Trainers 2021
 - 5.1.3 Mandate amendment
- 5.2 On-going Working Groups: BEF-1; REF-8(BPR) (10')

Item 6 – Updates on developments by Commission

15:00-15:50

- 6.1 Updates from DG SANTE on the BPR provisions (35')
- 6.2 Updates from DG GROW Working Group on Borderline between BPR and Cosmetic Regulation (15')

Item 7 – Activities in Member States and cooperation with other networks

16:00-16:30

- 7.1 Update from ADCO Chairs meeting and European Product Compliance network (10') BPRS Chair
- 7.2 NL Case study on European Court decisions for biocides (10')
- 7.3 SE paper on the efficacy of treated articles (10')

Item 8 - AOBs

16:30-16:40

- 8.1 Dates of next BPRS plenary meetings
- 8.2 Placeholder

Item 9 - Conclusions and action points

16:40-16:45



Annex 2: List of mandates of Forum / BPRS WGs adopted at the BPRS-12

Annex 2 a. "BPR enforcement project on treated articles BEF-1"

Chair: Jenny KARLSSON (SE) Vice Chair: Jabik DE BOER (NL)

BPRS Members/Alternates:

Francesca RAVAIOLI (IT)Heribert BURGY (CH)Marianne BRAAM (NL)

Invited Experts

- Karin PFAFF (DE)

- Nadine GRISEL (CH)

Fiona TCHANAKIAN (FR)

ECHA: Nicola TECCE

Objective:

- Conceive and manage the first major BPRS enforcement project on treated articles

Mandate:

- 1. Develop the project manual (guidance document, checklist, planning, recommendations) for the execution of the project
- 2. Prepare and deliver, if needed, the training for project national coordinators
- 3. Management of the Operational phase
- 4. Management the Reporting phase: Follow-up operational phase, collect the results and draft project evaluation
- 5. Cooperate with WG Train the trainers 2018 during the preparation and delivery of the content of the training
- 6. Elaborate tips and hints for inspectors based on the relevant outcomes from the project
- 7. Elaborate a questionnaire on gathering information on national enforcement activities from the BPRS members
- 8. Design and deliver an ad hoc workshop focused on the best practises of the BEF-1, if appropriate
- 9. Prepare and organize a short WebEx workshop for ECHA ASOs to present the results and recommendations from this project

Timeline:

- Assessment of needs and proposals to facilitate the project: Q1 2018
- Approve the scope by the BPRS: Q2 2018
- Project manual: Q4 2018
- Prepare and deliver the training for project national coordinators: Q4 2018
- Operational phase: 2019
- Reporting phase: 2020
- Questionnaire to be run after the BPRS-3
- Workshop with ASOs: April 2021
- BEF-1 workshop in June 2019



Annex 2 b. "Implementation of Interact BPR NEA"

(Mandate set inactive at BPRS-12)

Chair: Eugen ANWANDER (AT)

BPRS Members/Alternates:

- Francesca RAVAIOLI (IT)

Invited Experts:

- Natalija UMBRASIENE (LT)
- Brigitte EDER (AT)
- Jussi OLLIKKA (FI)
- Martin TRAUTNITZ (DE)

ECHA

- Emese SZÁNTÓ
- Anita TUOMAINEN

Objective:

- Support the implementation of the Interact Portal for NEAs for biocides (Interact BPR NEA) allowing inspectors access to data on biocidal products submitted to ECHA.

Mandate:

- 1. Analyse the requirements for the BPR inspectors;
- 2. Provide input during the further development and implementation of Interact BPR NEA;
- 3. Verify that the UAT conditions are implemented and follow up the implementation of the WG improvement requests;
- 4. Provide training on the use of the Interact BPR NEA to MSs;
- 5. Support the production of a Manual for using the Interact BPR NEA;
- 6. During the inactivity phase, no reporting at the BPRS meetings is required;
- 7. After resuming the WG activities, the reporting will be minimal, focusing on short presentations at the plenaries;
- 8. The WG will resume activities once timelines are known; no milestones yet set.

Timeline:

- To be reviewed by BPRS-14 (Q4 2021)



Annex 2 c. "BEF-2"

"BPR Enforcement Project on biocidal products containing nonapproved/approved active substances"

Chair: Jenny KARLSSON (SE)

BPRS Members/Alternates:

Heribert BUERGY (CH)
Cathrine SKJAERGARD (NO)
Eugen ANWANDER (AT)
Annemari LINNO (EE)
Helmut DE VOS (BE) – Chair of the TfT 2021

Invited Experts

Nadine GRISEL (CH)
Catherine BERTSCHY (CH)
Tobias SCHLEICHER (DE)
Mariana DE VRIES (NL)
Silvia NOBILE (IT)
Robert LJUNGGREN (SE)

ECHA: Nicola TECCE

Objective:

- Conceive and manage the second BPRS enforcement project on biocidal products containing non-approved/approved active substances

Mandate:

- 1. Defining the detailed scope of the BEF-2 in agreement with the BPRS members
- 2. Develop the project manual (guidance document, checklist, planning, recommendations) for the execution of the project
- 3. Prepare and deliver, if needed, the training for project national coordinators
- 4. Management of the operational phase
- 5. Management the reporting phase: follow-up operational phase, collect the results and draft project evaluation
- 6. Cooperate, if needed, with WG Train the Trainers during the preparation and delivery of the content of the training
- 7. Elaborate *Tips&Hints* for inspectors based on the relevant outcomes from the project
- 8. Elaborate a questionnaire on gathering information on national enforcement activities from the BPRS members, if needed
- 9. Design and deliver an ad hoc workshop focused on the best practises of the BEF-2, if appropriate
- 10. Prepare and organize a short WebEx workshop for ECHA ASOs to present the results and recommendations from this project
- 11. Prepare and deliver the training for national inspectors for the enforcement of the BPR (TfT 2021) in line with the scope of the BEF-2.

Timeline:

- Assessment of needs and project proposals: Q1 2021
- Approval of BEF-2 scope: Q1 2021
- Project manual: 04 2021
- Prepare and deliver the training for project national coordinators: Q4 2021



- Prepare and deliver the training for national inspectors (TfT): Q4 2021- Final

report of the TfT 2021: Q4 2021
- Operational phase: 2022
- BEF-2 workshop: Q2 2022
- Reporting phase: 2023

Reporting phase: 2023Workshop with ASOs: Q2 2024



Annex 2 d. Forum/BPRS Joint WG "MS reporting"

Forum Working Group "Member States reporting"

(mandate adopted at Forum-36/BPRS-11)

Composition

- Chair: Sinead MCMICKAN (IE)

Forum Members/Alternates

- Katja VOM HOFE (DE)
- Markus MAKI (FI)
- Elena ZIDAROVA (BG)
- Emilie RASOOLY (FR)

BPRS Members/Alternates

- Francesca RAVAIOLI (IT)
- Annemari LINNO (EE)
- Helmut DE VOS (BE)

Invited Experts

- Katja TRAWNY (DE)

COM: Ligia NEGULICI (DG SANTE)

ECHA: Maciej BARAŃSKI;

Objectives:

- Prepare the pilot for the Member States annual reports on enforcement as defined in Forum WP 2019-2023 and comment on the templates of the the Reports prepared by the Commission

Tasks:

- A. Review the templates for the reports to the European Commission required under Article 117(1) of REACH and Article 46(2) of CLP, Art 22(1) of PIC and art 65(3) of the BPR
- B. Liaise with COM consultant preparing the review reporting templates under the Art 117 of REACH, Art 46 of CLP and art 65(3) of BPR
- C. Draft the reporting template for annually reporting the Member States Enforcement activities under REACH and CLP
- D. Liaise with WG Interlinks regarding any data on interlinks to be included in the reports
- E. Start the pilot phase of the annual reporting exercise (Start postponed to 2021)
- F. Examine MS Report template under Art 65(3) and use it to draft a template for annually reporting the Member States Enforcement activities under BPR, for further consideration by the BPRS in November 2019
- G. Prepare the template for the report to the European Commission required under Article 13(1)(a) of the POPs Regulation
- H. Attempt to find a harmonised method of counting controls for the purposes of reporting by Forum and BPRS. (Postponed until further notice, following MB60 decision ECHA work plan)

Timeline: Forum-37 (March 2021)



Annex 2 e. Forum/BPRS Joint WG "REF-8"

Forum Working Group

Work Package A.1

"Coordinated enforcement project REACH-EN-FORCE-8"

(mandate adopted at Forum-37/BPRS-12)

Composition

Chair: Karin RUMAR (SE)

Forum Members and Alternates

- Eugen ANWANDER (AT)
- Martin MARKO (CZ)
- Maria PALEOMILITOU (CY)

Invited Experts

- Kevin BUCKLEY (IE)
- Sara YASSINE (DK)
- Timea TARNOCZAI (HU)
- Jurgita BALCIUNIENE (LT)
- Ingrida STULGIENE (LT)

BPRS Members and Experts

- Cathrine SKJÆRGÅRD (NO) (BPRS member)
- Francesca RAVAIOLI (IT) (BPRS member)
- Jenny KARLSSON (SE) (BPRS alternate)
- Brian MURPHY (IE) (BPRS alternate)
- Jabik DE BOER (NL) (BPRS alternate)
- Anne HORN (DE) (BPRS expert)

ECHA

- Tania MATEUS
- Magdalena TŁOCZEK
- Nicola TECCE

Objective:

- Conceive and manage the eighth major Forum enforcement project REF-8 'Enforcement of CLP, REACH and BPR duties related to substances, mixtures and articles sold on-line'.

Mandate:

- 1. Develop the project manual (guidance document, checklist, planning, recommendations) for the execution of the project, taking into account the learnings from previous Forum projects "control of internet sales" and "REF-4" and others at EU level;
- 2. Define the specific duties to be covered in the project;
- 3. Prepare and deliver the training for project national coordinators
- 4. Management of the Operational phase
- 5. Management the Reporting phase: Follow-up operational phase, collect the results and draft project evaluation
- 6. Elaborate tips and hints for inspectors based on the relevant outcomes from the project



7. Prepare and organize a short WebEx workshop for ECHA ASOs to present the results and recommendations from this project

Timeline

- Project manual: Q4 2019

- Prepare and deliver the training for project national coordinators: Q4 2019

- Operational phase: 2020

- Reporting phase (National Coordinators): Q1 2021

- Evaluation phase: Q3 2021

- Draft report: Q4 2021

Adoption of the report: Q4 2021Tips and hints for inspectors: Q2 2022

- Workshop with ASOs: Q2 2022