

$11^{ ext{TH}}$ plenary meeting of the BPR Subgroup of the Forum for Exchange of Information on Enforcement

BPRS-11

4-5 NOVEMBER 2020

REMOTE MEETING

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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 second 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) with the inclusion of one new item: "ECHA future" that was delivered by the deputy Executive Director of ECHA. Two AOBs were also included, i.e. 'Austrian case study on active chlorine', and 'update on the future plenary dates'. 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-10 were discharged. The item related to the cooperation between BPRS and BPC on risk management measures was postponed to the BPRS-12.

Item 2 – Discussion of the updated transparency proposals

A member of the HET updated the plenary on the ongoing project to improve the stakeholder perception of the BPRS/Forum activities. The topics that has been discussed so far aim at increasing transparency and having more active collaboration with the ECHA Accredited Stakeholders (ASOs).

The speaker updated the plenary on the decisions taken at the Forum-36 on the same matter and mentioned the concerning factors analysed during the discussion, i.e. potential leakage of internal information, relevance for Accredited Stakeholders, resource involvement from ECHA and MSs side.

The BPRS members agreed to implement the following proposals: i) publishing and maintaining the list of recommendations triggered by BPRS enforcement projects; ii) involving ASOs in future BEF projects when elaborating Working Groups mandates; iii) conducting remote workshops with ASOs after the publication of BEF project reports.

HET was tasked to implement the agreed proposals as of 2021. An update of the matter will take place at the next plenary meeting.

Item 3 - Updates on the cooperation with ECHA Statutory bodies and ECHA Secretariat

3.1 Elaboration of the Registry of Legal Duties of REACH, CLP, PIC, POP and BPR – Call for expressions of interest for BPRS

One member of the HET updated the BPRS members on the Forum/BPRS project focusing on the 'inventory of recommendations' triggered by harmonised enforcement projects. The creation of the inventory was recommended after the ECHA internal audit, and it has the goal to make the Forum and BPRS projects more impactful with stakeholders and the general public. The purpose of the inventory is to ensure that the recommendations addressed by the Forum/BPRS are eventually shared and followed up with the relevant recipients, i.e. ECHA, NEAS, ECHA ASOS, COM.

The BPRS agreed to include and publish the legal duties covered in the BPRS projects in



the Registry of Legal Duties of REACH, CLP, PIC, POP and BPR.

The BPRS nominated one member to join the WG Prioritisation of REF projects in order to support the periodic update of the concerned document with reference of BEF projects. The BEF-1 recommendations will be included in the inventory after the BPRS-11.

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

The Chair informed the BPRS about the discussions that took place during the remote meeting with the ECHA Directors held on 26 November. Among the topics discussed, the following were relevant to be shared with the BPRS members: update on ECHA multi annual financial framework budget and impact on ECHA resources, transparency activities of the Forum and BPRS, development of the ECHA policy on meetings of its statutory bodies, update on the UK withdrawal.

3.3 Update on the setting for future plenary meetings at ECHA

One member of the ECHA Secretariat informed the BPRS about the current work at ECHA on the policy regarding its committees and the ambition to reduce the number of physical plenary meetings in order to adapt to the reduction on the resources. The HET was tasked to inform the BPRS members on the future decisions that ECHA will take on this regard in the coming months.

3.4 ECHA Programming 2021-24 - "Choosing our future"

The ECHA Deputy Executive Director set the context for the ECHA programming for 2021-2024 and its related challenges, which are largely defined by the financial pressures and increasing activities of ECHA. In particular, the speaker touched upon the uncertainties on the ongoing multi annual financial framework (MFF) discussion, the estimated decrease in REACH fee income, and the increased expectations of ECHA resulting from the chemicals strategy.

The BPRS members were invited to coordinate with Forum members in their countries and liaise with the Management Board (MB) member indicating what the national priorities are in term of support from ECHA.

The HET will duly inform the BPRS members on the forthcoming decisions to be taken in term of ECHA resources allocated to the BPRS/Forum tasks.

Item 4 - Practical issues for enforcement

Issue BPRS 8.1 - Treated articles with permethrin

The practical issue focused on the enforceability of the labelling requirements for treated articles incorporating the active substance permethrin. After the fourth round of written comments the HET finalised the draft issue and submitted the Supplement of the Manual of Conclusion (MoC) to the BPRS members. No further comments were received, and the final written adoption of the issue was initiated accordingly (deadline set on 13 November). Once adopted the issue will be included in the related BPRS MoC.

Issue BPRS 9.1 - Borderline issue

The practical issue focused 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. After the fourth round of written comments the HET revised the draft



conclusion clarifying the implementation of the BPR with reference to the efficacy concept in conjunction with Article 3. The issue was also consulted with the ECHA Legal Affair Unit and the final version was submitted at the BPRS-11 where additional comments on the transitional measures were reported during the discussion by some BPRS members. The HET was tasked to revise the issue taking the new inputs into account and launch the final written adoption accordingly.

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

The issue focused 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. 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.

The ECHA Biocides Assessment Unit was consulted and suggested to escalate the discussion to the ECHA Coordination Group (CG). The originator of the issue is currently liaising with their Competent Authority for biocides in order to bring the topic at the next ECHA Coordination Group meeting. The BPRS members will discuss the feedback from the ECHA CG once available.

Item 5 - BPRS enforcement activities

5.1 - Implementation of Interact portal BPR

One member of the HET informed the plenary on the progress made with the latest test version of the Interact BPR that was made available to the WG members on 26 October 2020. The WG is performing the concerning tests of the platform in a stepwise approach, as different functionalities are made available at different times.

The speaker updated the plenary on the security model of Interact BPR that was discussed in the commenting round with the BPRS. The final approval of the model will take place in mid-December. The access to the platform will be granted after the approval of the security model; i.e. starting as of January 2021. In the new platform the biocidal product data will be available (some further additions will be implemented in February 2021).

The HET also informed the BPRS that the full audit of the platform will be performed every six years, instead of three years initially communicated.

The access to certain functionalities of the platform for invited experts will be available as of November 2020. The changes related to login in relation to different user groups were presented.

The speaker presented to the plenary the demo of the Consultation module of Interact BPR answering to questions raised by the BPRS members.

5.2 Working Groups progress reports not addressed at the plenary

BEF-1

The BPRS Chair informed the plenary that a WG Progress Report was submitted to the BPRS members. The reporting phase of the BEF-1 which focused on the labelling obligations for treated articles (TAs) and the presence of legal/illegal active substances is approaching its final stage. The final adoption and publication of the BEF-1 report is foreseen by beginning of December. The WG members are working with ECHA Communication Unit to elaborate communication products about the BEF-1 to be published



on the ECHA website. The WG Chair already presented the results of the BEF-1 during the Forum/BPRS Open Session with ASOs on 29 October 2020. Some of the key findings that were reported are: 22 countries participating to the BEF-1, 1187 companies and 1844 treated articles inspected, 83% of the enforcement visits were on-site, 73% of TAs inspected were produced in EU, and the most controlled categories of articles (as treated articles) were clothing (38%) and bedding (19%). Most of the TAs inspected were labelled, however, almost 50% of the articles checked didn't respect fully the concerned requirements of the BPR (e.g. missing information on biocidal active substances), while 23% of the mixtures inspected were found incompliant.

The WG members will elaborate the BEF-1 *Tips&Hints* during the beginning of 2021. The document will aim at supporting the national inspectors in future enforcement activities focused on TAs providing them the best practises and lessons learnt from the BEF-1.

Training for Trainers 2020

The Chair informed the plenary that the training event will be held remotely on 18 November 2020. The topics of the training are: "Definition of biocides: legal components and active substance approval; Decisions: availability of data and BPR borderline issues". The agenda and the setting of the training are reported in the WG Progress Report that was submitted to the BPRS members.

As follow-up of the event, the WG members will share with the participants the case studies with the correct reasonings, and the presentations to be delivered at the training. The training material will help the National Enforcement Authorities in arranging future national trainings in their countries.

REF-8 - BPR module

The BPRS Chair informed the plenary that the results of the survey run in September 2020 among the National Coordinators (NCs) of the REF-8 indicated that majority of the MSs are able to complete the REF-8 inspections by the end of 2020, as initially planned. Therefore, the WG recommended that the Forum and BPRS maintain the project timeline as agreed, allowing if needed some degrees of flexibility.

The adoption and publication of the REF-8 report is expected by the end of 2021.

Member States reporting

The Chair updated the plenary on the status of the activities performed by the WG. The COM was tasked to share for information the latest version of the Art 65(3) template with the BPRS members.

5.3 Establishment of the BEF-2

The Chair reminded to the plenary that at BPRS-3, while endorsing the BEF-1 on treated articles, the BPRS already agreed on a preliminary topic in view of the BEF-2, namely on 'biocidal products containing non-approved/approved active substances'.

At the BPRS-11, the BPRS agreed on the creation of the BEF-2 WG mandate and discussed how to refine the scope of the project. Some members proposed to focus the enforcement activities only on biocidal products authorised under the BPR regime, excluding products falling under national legislations (i.e. active substances pending EU approvals). Other BPRS members suggested adding extra modules on Article 95 and labelling.

The HET was tasked to gather written inputs after the plenary and to hand over the information collected to the newly established WG BEF-2.



The BPRS members were invited to nominate members for the BEF-2. The activities of the newly established WG will be kicked off in January 2021, and the operational phase of the project is expected in 2022.

5.4 Establishment of the WG Training for Trainers 2021

The BPRS agreed on the need for a future Training for Trainers to be held in 2021. This will be the fourth training event run under the umbrella of the BPRS.

The BPRS were invited to send in writing to the HET topic proposals, and to nominate members to join the for the newly created BPRS WG TfT 2021.

The training event will be probably held during the second half of 2021, and a synergy with the BEF-2 WG was recommended by the Chair of the BPRS.

Item 6 Debriefing Open Session and Cross-legislation issues

6.1 Update from Forum-36

The Forum Chair debriefed the plenary on the key issues tackled during the last plenary of the Forum (i.e. Forum-36). The group agreed on a pilot project on classification of mixtures including detergents and cleaning products. The transparency proposals were discussed during the plenary, and the members decided to involve ASOs in the preparatory phase of future enforcement projects. It was also decided to organise *ad-hoc* workshops after the publication of Forum project reports.

Regarding the on-going Forum WGs, the speaker updated the plenary on the REF-8 project, the MS Reporting and the Interlinks.

Other aspects reported by the BPRS Chair concerned the inputs related to enforcement practices that the Forum will provide in view of the forthcoming REACH review.

One BPRS member asked information on the Forum pilot project concerning the poison centres and the biocide product notifications. Clarifications were provided by the Forum Chair accordingly.

6.2 Debriefing from the joint Forum-BPRS open session with ASOs

The Joint Forum-BPRS Open session took place remotely on 29 October 2020. The Forum and BPRS members appreciated the high number of stakeholders attending the event (40 ASOs) and the various issues brought forward. Only one topic related to the BPR was presented by the European Biocidal Products Forum (EBPF) from Cefic.

The Forum Chair mentioned that the lines-to-take prepared by the HET and commented by the Forum and BPRS members served properly the purpose, making the discussion at the Open session fruitful and successful.

At the open session one ASO raised some technical questions on the Forum-BPRS's outcomes and invited the groups to improve project reports and recommendations, especially for the industry usability.

Some Forum members expressed the need of tackling ASO's questions well in advance of the Open session referred to their increasing complexity. The HET was invited to start the process of developing the agenda and the line-to-take earlier in time. A suggestion of decoupling the open session from the regular Forum plenary was also made.

Several Forum members suggested clarifying better the focus of the open sessions encouraging ASOs to bring topics for which a discussion with the groups would trigger beneficial and impactful responses.

Forum and BPRS members were invited to provide written feedbacks on the organisation of future Open sessions. A follow-up discussion will take place at the BPRS-12.

6.3 Update discussion on the cooperation on cross-legislation issues between Forum and BPRS



One member of the HET updated the BPRS on the progress of discussion since the BPRS-10. The current proposal foresees cross-legislation issues to be discussed in writing without involving Switzerland, as there is no mutual recognition agreement between COM and Switzerland for other legislations.

After the discussion, the HET was tasked to prepare a revised document clarifying the potential practice of splitting the BPR subjects from those of REACH/CLP/PIC/POP. The BPRS members will be invited to comment in writing the updated proposal after the plenary.

Item 7 - Updates on relevant developments by the European Commission

7.1 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 activities related to COVID-19 and its impact on biocides. Specifically, the speaker informed the plenary that Member States and industry associations reported no significant shortages in disinfectants since MSs have continued granting Art 55(1) derogations.

The speaker updated the plenary on the current delays in biocidal product authorisations, and the status of the renewal of anticoagulant rodenticides.

With regard to the Article 65(4) report on BPR implementation the speaker clarified that based on reports from Member States the Commission has to draw a composite report on the implementation of the BPR to be submitted to the Council and European Parliament by June 2021. Special attention will be given to treated articles and BEF-1.

Moreover, the presentation touched upon the 'Darie case' and its impact on concept of biocidal products as expressed by the European Court; the UK's withdrawal from the EU and the related work on the product authorisation procedures; and the state-of-play with the amendment of Annex II and III to the BPR.

After the presentation, some questions were addressed from the BPRS members to the COM representative concerning the consequences of the UK's withdrawal.

7.1.1 Clarification on face masks treated with biocides - Borderline between BPR and Medical Devices Regulation

The case of face masks treated with biocides was brought to the attention of the BPRS some weeks before of the plenary by one of its member. The issue focuses on the remit of the medical devices legislation and the BPR with reference to these items which are currently available on the EU market.

After the discussion on the practises in place in the NEAs, the DG SANTE representative clarified that a case-by-case analysis should always be performed in order to establish how to regulate face masks treated with biocides. The main criteria to consider in the evaluation are the (medical/biocidal) claims and the type of packaging (e.g. the indication of compliance with certain European standards plays an important role in addressing the related responsibilities). In case MSs decide that face masks fall under the BPR, the Commission guidance document on treated articles (i.e. CA-Sept13-Doc 5.1.e (Rev1) - treated articles guidance.doc) can help in identifying the primary biocidal function of a product, deeming it as biocidal product or, alternatively, as treated article or neither.

The COM's position on face masks was also brought to the attention of the HelpNet members in order to harmonise the line-to-take among the two bodies.

7.2 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 addressed the problems concerning leave-on hydroalcoholic gels, their current shortage on the market, and the related media attention. The speaker clarified that the situation in the MSs is highly diversified and there is a need of alignment on additional guidance on biocides/cosmetic claims. It is important to avoid the presence on the market of illegal and ineffective products. In this light it was reported that a COM working document is under finalisation by middle of November 2020. The BPRS will be informed in due time on its publication.

After the presentation, some BPRS members asked clarifications concerning the use of cosmetic claims on biocidal products, and requested the COM representative to be included in the commenting round before the finalisation and publication of the *ad hoc* document on claims of hand gels.

One BPRS member also shared their NEA experiences in enforcing illicit disinfectants on the market, and mentioned the usefulness of chemical analysis in specific circumstances to detect products efficacy.

7.3 State-of-play of the revised EU market surveillance regulation

A representative of DG GROW delivered to the plenary a presentation on the provisions established by the new market surveillance regulation (EU) 2019/1020, which will be in place on 16 July 2021. The new piece of legislation covers all the non-food products on the EU market, among which the ones regulated under REACH, CLP, POP and BPR. Following the principles of *lex specialis* the revised market surveillance regulation does not apply where already specifically regulated in product-specific legislations. The key objectives of the new legislation focus on: (i) improving controls at external borders; (ii) improving general compliance with the law of non-food products; (iii) addressing online sales; (iv) improving cooperation at national level with custom authorities, between MSs and EU-wide.

The speaker mentioned to the plenary that the cooperation across the Administrative Coordination Groups (ADCOs) will be also reinforced, in a synergy with the Product Compliance Network – PCN (first meeting scheduled on 22 January 2021).

The BPRS members will be informed on the forthcoming decisions and provisions which might be relevant for their work at the NEAs.

Item 8 - Activities in Member States and cooperation with other networks

8.1 Update from ADCO Chairs meeting

The key items to be discussed in the future ADCOs meetings focus on: (i) Union Testing Facilities; (ii) products entering the Union market (customs related provisions); (iii) Product Compliance Network (PCN); (iv) ICSMS; (v) Market Surveillance Indicators; (vi) General training needs for MSs.

The COM representative was tasked to verify whether the BPRS is to be considered as a separate ADCO with separate representation than Forum. In that instance, the BPRS agreed on mandating its Chair to represent the Subgroup at the ADCO Chairs and product compliance network meetings.

Item 9 - AOBs

9.1 Update on 'disinfection-gates for individuals'

One BPRS member updated the plenary about the discussion that took place via email among the BPRS members on the enforcement case of 'disinfection-gates for individuals'.



At the beginning of October 2020 some NEAs reported the enforcement of some non-authorised use of biocidal products belonging to PT 1, namely ozone generated in situ, ethanol 62% and 2-Propanol 10%. Specifically, the illicit use consisted in gates spraying disinfecting liquids at the entrance of supermarkets where customers could voluntarily walk through. Concerned citizens initially reported the cases to the related NEAs, which immediately removed the tools after inspections.

In this light, the World Health Organisation (WHO) indicated that spraying small drops/mist of disinfectants directly on people (biocidal product PT 1) is not effective against the spread of the COVID-19 pandemic, and those tools should not be used being also a potential source of risk for human health.

The DG SANTE representative was tasked to express their view in writing after the plenary.

9.2 AT case study - Active chlorine hand disinfectant

Due to time constrain the case study was not presented at the plenary and the HET was tasked to distribute the AT presentation to the BPRS members. If interested, members will provide their feedbacks in writing directly to the BPRS AT member.

9.3 Future BPRS plenaries dates

The tentative dates for the BPRS meetings in 2021 are the following: (i) BPRS-12: 23-24 March (remote); (ii) BPRS-13: 22-23 June (remote); (iii) BPRS-14: 8-12 November (to be confirmed whether remote or physical meeting).



II. Conclusions & action points adopted at the BPRS-11 (public version)

| Agenda point | Conclusions / decisions / minority opinions | Action requested after the meeting |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Item 1- Welcome an | | • |
| 1.2 Adoption of the Agenda | Agenda was adopted | |
| Item 2 – BPRS and | Forum's transparency | |
| 2.1 Discussion of the updated transparency proposals | n the commention with FOLIA St | |
| - | n the cooperation with ECHA St | atutory bodies and |
| 3.1 Elaboration of the Registry of Legal Duties of REACH, CLP, PIC, POP and BPR – Call for expressions of interest for BPRS 3.2 Debriefing from the meeting with ECHA Directors and Forum/BPRS Chairs 3.3 Update on the setting for future plenary meetings at ECHA 3.4 ECHA Programming 2021-24 – "Choosing our future" | The BPRS agreed to include and publish the legal duties covered in the BPRS project in the Registry of Legal Duties of REACH, CLP, PIC, POP and BPR covered in Forum/BPRS projects. | HET will distribute the minutes of the meeting with ECHA Directors when they have been finalised. BPRS members are invited to coordinate with Forum members in their countries and liaise with the Management Board member indicate what are the national priorities for support for the Forum/BPRS needed from ECHA. HET will arrange an update on this matter at one of the future plenary meetings. |



| Agenda point | Conclusions / decisions / | Action requested after | | |
|-------------------------------------------|----------------------------------|--------------------------------------------|--|--|
| | minority opinions | the meeting | | |
| Item 4 – Practical issues for enforcement | | | | |
| 4.1 Items raised by | | BPRS members are invited | | |
| the | | to submit new practical | | |
| BPRS/ECHA/COM | | issues by 1 February 2021. | | |
| Practical issue 9.1 | | DE and AT BPRS members | | |
| | | are invited to submit | | |
| | | specific comments by 20 November. | | |
| | | November. | | |
| | | HET will revise the practical | | |
| | | issue and consult with the | | |
| | | BPRS | | |
| Practical issue 10.1 | | FR BPRS member is invited | | |
| | | to liaise with FR BPR CA so | | |
| | | that the topic is tabled at | | |
| | | the ECHA Coordination Group by 13 November | | |
| | | Group by 13 November | | |
| | | BPRS members are invited | | |
| | | to liaise with their | | |
| | | Coordination Group | | |
| | | members to provide | | |
| | | enforcement input for the | | |
| | | discussion. | | |
| | | HET will verify the timelines | | |
| | | of the ECHA Coordination | | |
| | | Group meeting and inform | | |
| | | the BPRS when the issue | | |
| | | may come back to the BPRS | | |
| | | by 20 November | | |
| Item 5 – BPRS enfo | rcement activities | | | |
| 5.1 Implementation | | | | |
| of Interact portal BPR | | | | |
| 5.1.1 WG progress | | | | |
| report | | | | |
| 5.1.2 Update on | | | | |
| Interact BPR NEA | | | | |
| 5.1.3 Interact | | | | |
| Consultation | | | | |
| module | | | | |
| 5.1.4 Mandate | The BPRS has revised the mandate | | | |
| amendment | of the WG. | | | |
| 5.2 WG progress | | COM will share the latest | | |
| reports not | | version of the Art 65(3) | | |
| addressed at the | | template for information of | | |
| meeting (15'): | | the BPRS members by 15 | | |
| BEF-1; Training for | | December | | |
| enforcement | | | | |



| Agenda point | Conclusions / decisions / minority opinions | Action requested after the meeting |
|------------------------------------------------------------------------------------------------------------|------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| trainers 2020; REF- 8 on-line sale/BPR module; MS Reporting | Timority opinions | BPRS members are invited to vote in the written adoption on the BEF-1 final report after it is sent out in mid-November. |
| 5.2.1 Mandates amendment/closur e | The BPRS revised the mandates | Tilla Novemberi |
| 5.3 Establishment of the WG BEF-2 | | |
| 5.3.1 Mandate creation | The BPRS established the WG and adopted the mandate. | |
| 5.4 Establishment of the WG Training for Trainers 2021 | | BPRS members are invited to indicate whether the training event 2021 is needed and if so submit proposals for the preferred topics by 15 January 2021 |
| 5.4.1 Mandate creation | | |
| | Dpen Session and Cross-legisla | tion issues |
| 6.1 Update from Forum-36 | | |
| 6.2 Debriefing from the joint Forum/BPRS open session with ASOs | | BPRS members to provide the feedback on the open session and indicate whether a virtual open session could be decoupled from the BPRS plenary by 30 November HET and Chairs will |
| | | implement the recommendations from the Forum/BPRS when preparing the next open session. |
| 6.3 Update discussion on the cooperation on cross-legislation issues between Forum and BPRS | | HET will prepare a revised document explaining the alternative discussed during the meeting i.e. to continue along the existing practice of splitting the BPR subjects from those of REACH/CLP/PIC/POP by 27 November |
| | | BPRS members will be invited to comment on the proposal and after that vote on it in written procedure. |



| Agenda point | Conclusions / decisions / minority opinions | Action requested after the meeting |
|---------------------------------------|---------------------------------------------|------------------------------------|
| Item 7 Updates on developments by COM | | |
| 7.1 Updates on the | | |
| BPR provisions | | |
| 7.1.1 Clarification | | |
| on face masks | | |
| treated with | | |
| biocides - | | |
| Borderline between | | |
| BPR and Medical | | |
| Devices Regulation | | |
| 7.2 Updates from | | |
| DG GROW Working | | |
| Group on | | |
| Borderline between | | |
| BPR and Cosmetic | | |
| Regulation | | |
| 7.3 State-of-play of | | |
| the revised EU | | |
| market surveillance | | |
| regulation | | |
| | Member States and cooperatio | n with other networks |
| 8.1 Update from | • | COM will verify whether the |
| ADCO Chairs | | BPRS is to be considered as |
| meeting | | a separate ADCO with |
| | | separate representation. If |
| | | so COM to take note of |
| | | representation agreed by |
| Item 9 AOB | | the BPRS. |
| 9.1 Update on | | COM is invited to express its |
| 'disinfection-gates for | | position regarding the use of |
| individuals' | | "disinfection gates for |
| | | individuals" by 23 December |
| | | 2020 |
| 9.2 AT case study - | | HET will distribute the AT |
| Active chlorine hand | | presentation on this matter |
| disinfectant | | by 13 November |
| | | BPRS members will provide |
| | | their feedback on the matter |
| | | to AT member and HET by |
| | | 23 December |
| 9.3 Future BPRS | | HET will send the updated |
| plenaries dates | | information on BPRS |
| | | meeting dates for 2021 by |
| | | 13 November |
| Item 9 – Adoption o | f conclusions and action points | |



III. List of attendees of the BPRS-11

BPRS members

| | Country | Name |
|----|---------|------------------------------|
| 1 | AT | ANWANDER Eugen |
| 2 | CY | ELIA Nikos |
| 3 | CZ | JAROLIM Oldrich |
| 4 | DE | SCHROETER Meike |
| 5 | DK | HANSEN Lise Bach |
| 6 | EE | LINNO Annemari |
| 7 | EL | PAPATHANASIS Thanasis |
| 8 | ES | TEBAR LUJAN Jorge |
| 9 | FI | MÄKI Markus |
| 10 | FR | VERDIER Elodie |
| 11 | HR | PILETIC Kaca |
| 12 | HU | DEIM Szilvia |
| 13 | IE | MURPHY Brian |
| 14 | IS | INGVARSDOTTIR Hafdis Inga |
| 15 | IT | RAVAIOLI Francesca |
| 16 | LI | RELLA-QUADERER Maria-Rosaria |
| 17 | LT | HAKAITE Palmira |
| 18 | LV | NEIMANE Jana |
| 19 | LU | HERMES Joe |
| 20 | MT | GARG Ramandeep |
| 21 | NL | BRAAM Marianne |
| 22 | NO | SKARGARD Cathrine |
| 23 | PL | WASIK Romualda |
| 24 | PT | DIAS Marina |
| 25 | SE | KARLSSON Jenny |
| 26 | SI | HAJRLAHOVIC-MEHIC Semira |
| 27 | SK | POCAROVSKA Miriam |

Invited Experts

| | Country | Name |
|---|---------|---------------|
| 1 | CH | GRISEL Nadine |

Advisers

| | Country | Name |
|---|---------|-------------------|
| 1 | AT | EDER Brigitte |
| 2 | DE | WURSTHORN Sibylle |
| 3 | DE | FRENZEL Stefan |
| 4 | DK | MADSEN Betina |
| 5 | FR | TCHANAKIAN Fiona |



| | Country | Name |
|---|---------|-------------------|
| 6 | HR | SUVAK Zdenko |
| 7 | MT | AZZOPARDI Bernice |
| 8 | NL | DE BOER Jabik |

European Commission representatives

| | Country | Name |
|---|----------|-------------------|
| 1 | DG SANTE | NEGULICI Ligia |
| 2 | DG GROW | DEURWAARDER Ewout |
| 3 | DG GROW | SCAZZOLA Roberto |

ECHA's Harmonised Enforcement team staff

| | ECHA | 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 | KRYCHEVSKA Olena | Support and Enforcement |
| 6 | NIKULA Terhi | Support and Enforcement |
| 7 | TECCE Nicola | Support and Enforcement |
| 8 | TLOCZEK Magdalena | Support and Enforcement |
| 9 | TUOMAINEN Anita | Support and Enforcement |



IV. List of Annexes

Annex 1. Adopted agenda of BPRS-11

Annex 2. List of mandates of Forum /BPRS WGs

- 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 11th meeting of the BPR Subgroup of the Forum

4 November 10:30 - 15:00 (Helsinki time) 5 November 10:30 - 14:30 (Helsinki time)

Item 1 – Welcome and Introduction

10:30-10:45

- 1.1 Opening by the BPRS Chair and practicalities of remote meeting
- 1.2 Adoption of the Agenda
- 1.3 Declarations of conflict of interest with regard to the agenda items
- 1.4 Action points and written procedures from BPRS-10

For information/adoption

Item 2 – BPRS and Forum's transparency

10:45-11:30

2.1 Discussion of the updated transparency proposals (45')

For discussion/adoption

Item 3 - Updates on the cooperation with ECHA 11:40-12:25 Statutory bodies and ECHA Secretariat

- 3.1 Elaboration of the Registry of Legal Duties of REACH, CLP, PIC, POP and BPR Call for expressions of interest for BPRS (15') *HET member*
- 3.2 Debriefing from the meeting with ECHA Directors and Forum/BPRS Chairs (10') BPRS Chair
- 3.3 Update on the setting for future plenary meetings at ECHA (20') ECHA Secretariat

For information/agreement

Item 4 - Practical issues for enforcement

12:45-14:00

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

For discussion/adoption

Item 5 - BPRS enforcement activities

14:10-15:00

- 5.1 Implementation of Interact portal BPR (50')
 - 5.1.1 WG progress report WG Chair
 - 5.1.2 Update on Interact BPR NEA HET member
 - 5.1.3 Interact Consultation module HET member
 - 5.1.4 Mandate amendment

End of DAY 1 Start of DAY 2

Item 3.4 ECHA Programming 2021-24 – "Choosing our 10:30-10:45 future"

Speech delivered by the ECHA Deputy Executive Director (15')



Item 5 – BPRS enforcement activities

10:45-11:25

- 5.2 WG progress reports not addressed at the meeting (15'): BEF-1; Training for enforcement trainers 2020; REF-8 on-line sale/BPR module; MS Reporting
 - 5.2.1 Mandates amendment/closure
- 5.3 Establishment of the WG BEF-2 (20')
 - 5.3.1 Mandate creation
- 5.4 Establishment of the WG Training for Trainers 2021 (5')
 - 5.4.1 Mandate creation

For discussion/adoption

Item 6 – Debriefing Open Session and Cross-legislation 11:35-12:20 issues

- 6.1 Update from Forum-36 (10') Forum member
- 6.2 Debriefing from the joint Forum/BPRS open session with ASOs (15') Forum Chair/BPRS Chair
- 6.3 Update discussion on the cooperation on cross-legislation issues between Forum and BPRS (20') *HET member*

For information/agreement

Item 7 - Updates on developments by COM

12:20-14:05

- 7.1 Updates from DG SANTE on the BPR provisions (20')
- 7.1.1 Clarification on face masks treated with biocides Borderline between BPR and Medical Devices Regulation (10')
- 7.2 Updates from DG GROW Working Group on Borderline between BPR and Cosmetic Regulation (25')
- 7.3 State-of-play of the revised EU market surveillance regulation (30') DG GROW, Free movement of goods Unit

For information/discussion

Item 8 – Activities in Member States and cooperation 14:05-14:15 with other networks

8.1 Update from ADCO Chairs meeting (10') - BPRS Chair

Item 9 – AOB 14:15-14:25

9.1 Update on 'disinfection-gates for individuals' (10') - BPRS Chair

Item 10 – Adoption of conclusions and action points 14:25-14:30

End of BPRS-11 14:30



Annex 2: List of mandates of Forum /BPRS WGs

Annex 2 a. BPRS Working Group - BPR enforcement project - BEF-1

"BPR enforcement project on treated articles"

(Mandate amended at BPRS-11)

Composition

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
- BEF-1 workshop in June 2019
- Workshop with ASOs: Q2 2021



Annex 2 b. BPRS WG - Training for enforcement trainers 2020

BPRS Working Group "Training for enforcement trainers 2020"

(Mandate amended at BPRS-11)

Composition

Chair: Helmut DE VOS (BE)

BPRS Members/Alternates:

- Heribert BUERGY (CH)
- Eugen ANWANDER (AT)
- Jenny KARLSSON (SE)

Invited Experts:

- Nadine GRISEL (CH)
- Silvia NOBILE (IT)
- Nils MANEGOLD (DE)
- Marcus MORENO-HORN (DE)

ECHA

- Nicola TECCE

Objective

Prepare and deliver the training for trainers on the enforcement of the BPR in the fourth quarter of 2020.

Mandate

- 1. Examine the training subjects relevant for enforcement and prepare the priority topics/draft agenda for agreement by end of April 2020
- 2. Specify the envisaged level of the content of the training
- 3. Prepare materials necessary for the training such as presentations or documents
- 4. Actively conduct the training event with support from other BPRS members, ECHA and COM and other experts in specific topics as necessary
- 5. Collect, summarise and evaluate the recommendations and reactions of participants

Timeline

- By the end of April 2020: conclude on list of subjects and prioritisation, adopt the agenda of the training event
- By end of 2020: Final report adopted via written procedure



Annex 2 c. Interact Portal

BPRS Working Group "Implementation of Interact BPR NEA"

(Mandate amended at BPRS-11)

Composition

Chair: Eugen ANWANDER (AT)

BPRS Members/Alternates:

- Francesca RAVAIOLI (IT)

Invited Experts:

- Natalija UMBRASIENE (LT)
- Jurgen SCHMID (DE)
- Brigitte EDER (AT)

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.

Timeline:

- BPRS-12 (Q1 2021)



Annex 2 d. Forum/BPRS WG - REF-8

Forum Working Group

Work Package A.1

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

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

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 member)
- Brian MURPHY (IE) (BPRS alternate)
- Jabik DE BOER (NL) (BPRS alternate)
- Anne HORN (DE) (BPRS expert)

ECHA

- Tania MATEUS
- Aleš FRONTINI
- 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 2021

- Tips and hints for inspectors: Q4 2021

- Workshop with ASOs: Q2 2022



Annex 2 e. Forum/BPRS 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; Aleš FRONTINI

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
- 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.

Timeline: Forum-37 (March 2021)



Annex 2 f. BPRS WG - BEF-2

BPRS Working Group

BEF-2

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

(mandate adopted at the BPRS-11)

Composition

Chair: Jenny Karlsson (SE)

BPRS Members/Alternates:

- Heribert Buergy (CH)
- Cathrine Skjaergard (NO)
- Eugen Anwander (AT)

Invited Experts

- Nadine Grisel (CH)
- Tobias SCHLEICHER (DE)

ECHA: Nicola TECCE; Ales FRONTINI

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

Timeline:

- Assessment of needs and project proposals: Q1 2021
- Approval of BEF-2 scope: Q1 2021



Annex 2 g. BPRS WG - Training for enforcement trainers 2021

BPRS Working Group

"Training for enforcement trainers 2021" (mandate adopted at the BPRS-11)

Composition

Chair:

BPRS Members/Alternates:

Invited Experts

ECHA

- Nicola TECCE; Ales FRONTINI

Objective:

- Prepare and deliver the training for national inspectors or the enforcement of the BPR

Mandate

- 1. Examine the training subjects relevant for enforcement and prepare the priority topics/draft agenda for agreement by Q1 2021
- 2. Specify the envisaged level of the content of the training
- 3. Prepare materials necessary for the training (presentations and case studies)
- 4. Actively conduct the training event with support from other BPRS members, ECHA and COM and other experts in specific topics as necessary
- 5. Collect, summarise and evaluate the recommendations and reactions of participants

Timeline

- List of subjects and priority: Q1 2021
- Adoption of agenda of the training event: Q2 2021
- Delivery of the training: Q3 2021
- Final report adopted: Q4 2021



Annex 2 h. Forum WG Prioritisation

Forum Working Group Work Package A.1 "Prioritisation of REF Projects"

(Mandate adopted at Forum-36 and BPRS-11)

Composition

Chair: Oldrich JAROLIM (CZ) – rotating Chair

Forum Members/Alternates

- Maria ORPHANOU (CY) from June 2021
- Abdulqadir SULEIMAN (NO)
- Semira HAJRLAHOVIĆ MEHIĆ (SI)
- Markus MAKI (FI)

Invited Experts

- Tamas KOVACS (HU)
- Laura WILMS (DE)
- Rui CABRITA (PT)

Ad-hoc invited experts from BPRS (cooperating in the elaboration of the Registry of legal obligations subject to previous enforcement projects).

Jenny Karlsson (SE)

ECHA

- Juan Pablo CALVO TOLEDO

Objective:

- Propose annually the subject for the next harmonised enforcement project coordinated by the Forum (REF Projects).

Mandate:

According to the working procedure for the prioritisation and selection of REF projects, the WG shall:

- Review annually a list of proposals for REF projects submitted by Forum members, ECHA Secretariat, the Commission and the Stakeholder Organisations accredited by ECHA (ASOs);
- 2. Prioritise the subjects by applying Forum's methodology for the prioritisation, selection and management of REF projects
- 3. Draft a recommendation proposing the subject for the next REF project
- 4. Elaborate and update an inventory of project recommendations and a registry of legal obligations subject to previous enforcement projects in the following regulatory areas: REACH, CLP, PIC, POP, BPR.
- 5. Propose to the Forum topics for pilot and small-scale projects as an output of the prioritisation exercise where appropriate.
- 6. In addition, the WG will revise, when needed, the methodology for the prioritisation, selection and management of REF projects and implementing its working procedures to be adopted by the Forum.

The WG will operate from Forum-31 (November 2018) until the end of 2023 (end of the Forum MAWP 2019 - 2023). The mandate of the WG can be renewed to operate after this period.



Timeline:

- The basic timeframes are regulated by the Forum Methodology on Prioritisation and Selection of Project Proposals and the working procedure for the prioritisation and selection of harmonised enforcement projects coordinated by the Forum
- Shortlist of subjects for REF-11 by Forum-39.