

# MINUTES

# EIGHT MEETING OF THE BPR SUBGROUP OF THE

# FORUM FOR EXCHANGE OF INFORMATION ON ENFORCEMENT

**BPRS-8** 

20 JUNE 2019

ECHA, Helsinki (FI)

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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, a 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  |
| СОМ      | European Commission   |
| DG       | Directorate General at the Commission                                   |
| DG SANTE | Directorate General on Health and Food Safety/European Commission       |
| 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            |
| ICSMS    | Internet-supported information and communication system for the pan-    |
|          | European market surveillance  |
| MAWP     | Multiannual Work Programme  |
| MOC      | Manual of Conclusions   |
| MS       | Member State  |
| NC       | National Coordinator of the Enforcement Project                         |
| NEA      | National Enforcement Authority  |
| PD-NEA   | Portal Dashboard for National Enforcement Authorities - the successor   |
|          | system to RIPE  |
| RAPEX    | Rapid Alert System  |
| REACH    | Regulation (EC) No 1907/2006 concerning the Registration, Evaluation,   |
|          | Authorisation and Restriction of Chemicals                              |
| REF      | REACH-EN-FORCE, Coordinated Enforcement Project of the Forum            |
| ROPs     | Rules of Procedure  |
| SPC      | Summary of Product Characteristics                                      |
| ТА       | Treated Articles  |
| TF       | Task Force of the Forum/BPRS  |
| WG       | Working Group of the Forum/BPRS   |
| WIN PPIE | ECHA Work Instruction - Processing Practical Issues for Enforcement     |



# I. Summary record of the proceedings

The items reported in the minutes refer to the final agenda adopted at the BPRS-8 (Content IV, Annex I).

# Item 1 – Welcome and introduction

# 1.1 Opening by the Chair of the BPRS

10 The Chair of the BPRS welcomed the participants and opened the meeting. The plenary 11 was held at the ECHA premises in Helsinki, Finland.

12 He announced apologies, proxies, participating invited experts, advisers and COM 13 representative. The quorum requirement was met.

The Chair debriefed the plenary about the workshop on the BEF-1, which was held on 19 June afternoon at ECHA. More details about the event were shared under item 7 of the BPRS-8.

17 The Chair announced that the meeting was recorded for the purpose of writing the 18 minutes. The recordings are going to be destroyed after the minutes are adopted.

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# 20 **1.2 Introduction of the new HoU of A2**21

The Chair introduced the new manager of the Support and Enforcement Unit who started working at ECHA on 3 June 2019. Mr Annys Erwin (BE) gave an overview of his career and shared with the members the interesting pathway which led him to ECHA.

The Chair welcomed the continuation of the good cooperation between the BPRS and the
Support and Enforcement Unit in view of the future challenges of the next years.

# 1.3 Adoption of the agenda

The Chair informed the plenary about a new agenda item concerning the cooperation
between BPRS and BPC on risk management measures, and two room documents
circulated to the members.

The final agenda was adopted with the inclusion of an AOB requested by the Austrian BPRS
 member related to the availability of information on applications for Union Authorisations
 to the NEAs.

# 1.4 Declarations of conflicts of interest with regard to agenda items

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39 No conflicts of interest (according to Article 9(2) of the Forum Rules of Procedure - ROPs)
40 were declared at the meeting.

# 41 42 43 **1.5 State of play with regard to the action points from BPRS-7**

The ECHA Forum Secretariat informed the plenary on the status of the action points from
the BPRS-7 (document ECHA/BPRS-8/2019/1.5). Almost all the actions were discharged,
and three of them were to be addressed in the agenda items of the BPRS-8.

The ECHA Forum Secretariat informed the plenary also on three action points which were
pending from the BPRS-6.

#### 50 **1.6 Report of the written procedures and other issues between BPRS-7 and** 51 **BPRS-8** 52

53 The Chair informed the BPRS that a meeting document (i.e. ECHA/BPRS-8/2019/1.6) 54 reported the results of the written procedures that took place since BPRS-7.



# 55 Item 2 - Address by ECHA Deputy ED– Mr Jukka Malm

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57 The Chair introduced Mr Malm Jukka (FI) who is the Deputy Executive Director of ECHA. 58 In his welcome speech Mr Malm touched upon the ECHA reorganisation 2019, and the 59 activities of the ECHA Directorate A, i.e. "Submissions and Interaction". This is the 60 Directorate where the Unit A2 belongs, and that covers all the horizontal work with 61 enforcement authorities, support to industry and communication to the general public.

62

The speaker further highlighted the need to tighten the cooperation among the NEAs in order to cope the challenging of the future years. He mentioned the importance of the Forum/BPRS strategic plan for the 2019-2023, and the relevance of the new cooperation with the Biocidal Product Committee on the enforceability of risk mitigation measures. The expertise of the BPRS in enforcement of provisions of BPR and the national biocides legislations is a very important asset that could make the regulatory risk management more enforceable and therefore more impactful.

69 70

Finally, Mr Malm encouraged the BPRS to consider annual reporting on BPR enforcement activities to ECHA, to mirror the pilot phase installed by the Forum regarding REACH and CLP. He emphasised the value of the annual reporting as a good advertisement tool of the work performed by the NEAs. He encouraged the BPRS members to observe the results from the Forum test phase and to consider the future involvement of the BPRS.

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# 77 Item 3 – Update and cooperation with the Forum

# 79 **3.1 Updates from Forum activities**

One of the members of the BPRS briefly summarised, on behalf of the Chair of the Forum,
the subjects discussed at the Forum-33, which ended the afternoon of 19 June 2019.

The key messages relevant for the BPRS were focused on the common activities that the two groups are currently tackling. This included a quick update on the enforcement project (REF-8) on online sales, on the REF-6 on Classification and Labelling, on the preparatory activities for the next 'training for trainers' event, and on the new collaboration platform in Interact portal presented to the Forum members. Further discussion among the BPRS members took place under the agenda item 7 of the BPRS-8.

90 The second relevant point was an update from the discussion of a joint REACH-BPR 91 practical issue to be covered under item 5 of the BPRS-8. 92

Finally, the BPRS mandated the AT BPRS member to represent the group at the meetings
of the European cooperation on market surveillance (Administrative Cooperation Groups AdCos), while the LU BPRS member will participate to the meetings of the ICSMS Working
Group organised under the umbrella of the Commission.

# 98 3.2 Update from the cooperation between BPRS and BPC on risk management 99 measures

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The Chair of the Biocidal Product Committee (BPC) updated the plenary about the status
 of the collaboration between the BPC and the BPRS on the enforceability of risk mitigation
 measures (RMMs) proposed in applications for approval of an active substance and in
 Union authorisations of biocidal products.

105 After the BPRS-7, the BPC Secretariat analysed the adopted BPC opinions issued so far by

- 106 the body at ECHA, and created a list of concerned RMMs / label provisions on which the
- BPRS will be consulted. The document is now tabled for discussion at the next BPC plenary
- 108 meeting to be held on 25-26 June 2019.



109 The Chair of the BPC also mentioned to the plenary the need for the BPC to revisit some 110 of these RMMs / label provisions in order to increase consistency for certain categories of 111 substances.

112

113 The Forum Secretariat will launch the consultation with the BPRS members of the concerned list once approved by the BPC members. 114

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#### 116 Item 4 – Debriefing of the meeting with ECHA Directors by BPRS Chair

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118 The Chair debriefed the plenary about the meeting with ECHA Directors that took place on 119 17 June at ECHA. The key topics were related to the REACH evaluation action plan (REAP), 120 and to Authorisations and Restrictions under REACH. No BPR issues were discussed.

121 For sake of example the Chair of the BPRS mentioned to the members the points related 122 to the BPR which were discussed in previous Directors meetings. The Forum Secretariat 123 will share these points via email with the BPRS members before asking for new agenda 124 items for the next Directors meeting before the BPRS-9. 125

#### 126 Item 5 – Practical issues for enforcement

#### 127 128 5.1 Items raised by the BPRS/ECHA/COM

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#### - Issue 3.1 - Article 3(3) decisions (horse rug as a biocidal product) 131

132 At the BPRS-3 the Commission representative communicated that the Commission's legal 133 service decided that no transitional period is allowed for Article 3(3) decisions.

134 At the BPRS-7 it was decided to reopen the Issue 3.1 about the Commission's decision on 135 'horse rugs impregnated with permethrin'. The BPRS members tasked the Forum 136 Secretariat to revise its conclusion together with the originator of the Issue and the ECHA 137 Legal Affair Unit / COM.

138 The new revised conclusion was consulted twice with BPRS members before its written 139 adoption by consensus. The issue is now reported in the related BPR Manual of 140 Conclusions.

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#### 142 - Issue BPRS 5.1 – Is the refilling or repackaging of an authorised biocidal 143 product allowed under the BPR before the product is placed on the market?

144

145 The Forum Secretariat presented the status of the issue. The Practical Issue went through 146 six round of written consultations before the BPRS-8. Based on the last comments 147 suggesting the cancellation of the issue (see Annex 3) the Forum Secretariat internally 148 consulted the ECHA Legal Affair Unit and the Biocides Unit. After the discussion at the 149 plenary the members decided to close the Issue as it is currently conceived, and tasked 150 the Forum Secretariat to propose a new simple practical issue to reflect the outcome of 151 the discussion.

152

#### 153 - Issue BPRS 8.1 – Treated articles 154

155 The Forum Secretariat introduced the new practical issue submitted by Germany. The 156 Issue is focused on the enforceability of the labelling requirements for treated articles 157 incorporating the active substance permethrin.

158 After the discussion at the plenary, the BPRS decided that further analysis on the 159 conclusion is needed. The Forum Secretariat will follow up the Issue after the BPRS-8. 160

#### 161 - Joint Issue Forum/BPRS

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163 One member of the Forum Secretariat informed the plenary on the Forum Practical Issue 164 31.2 on creosotes, which also involves some aspects of the BPR. The Forum discussed how 165 to treat joint REACH/BPR issues and decided that further analysis among the Forum 166 Secretariat, BPRS and Forum will take place after the Forrum-33/BPRS-8.

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# 168 Item 6 – Updates on relevant developments by the European Commission

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# 170 **6.1** General updates on the BPR provisions by the European Commission 171

The COM representative (DG SANTE) gave an update of the COM's activities that were relevant for the work of the BPRS. In particular the presentation touched upon the application of Unique Formula Identifier (UFI) to biocidal products; the protection of cultural heritage and the potential derogation of the Article 55(3) of the BPR; the on-going work related to the renewal of active substances; the update of the information requirements of the BPR; the status of work on the in situ biocidal products; and the release of the guidance on the biocide product family (BPF).

179

180 Moreover, the speaker debriefed the plenary on the workshop held on 19 June at DG 181 SANTE in Grange (IE) on the 'Fact finding missions for biocides'. The main concerns related 182 to enforcement activities which were highlighted in the final report were: wide range of 183 products to control at MS's level and several authorities involved in the process (co-184 operation and co-ordination); difficulties in identify borderline products; e-commerce of 185 biocidal products; and treated articles.

186

Moreover, during the discussion that followed the presentation, the BPRS tasked COM to
 investigate the impact of the new Regulation 2019/515 on mutual recognition of goods on
 the BPR mutual recognition mechanism. The COM will inform the BPRS at the next plenary
 meeting.

# 191192 Item 7 - BPRS enforcement activities (on-going projects)

193

# 194 **7.1 - First BPR enforcement project BEF-1**195

# 196 **7.1.1 WG progress report**197

198 The Chair of the BPRS WG "First BPRS enforcement project on Treated Articles (BEF-1)" 199 introduced the work done by the WG and its conclusions since March 2019 (BPRS-7).

The BEF-1 is in the middle of its operational phase, and the WG members are supporting the NCs when needed. Inspections of treated articles are currently taking place in the MSs involved in the project.

On 19 June afternoon the WG delivered to the BPRS members and NCs an *ad hoc* workshop focused on the best practises of the BEF-1. The workshop was useful for the BPRS members / NCs to share their problems and discuss the national practises in enforcing treated articles. The most common challenge was the decision whether a product is a treated article or a biocidal product.

As main outcome of the BEF-1 workshop the WG will elaborate a record of the discussion in order to support the NCs in their duties during the course of the second half of 2019 (agenda of the workshop reported in Annex 3 to this document).

211

The Chair of the BPRS reminded the BPRS members and the NCs to send to the WG BEF-1 any reflection or observation coming from the experience in enforcing treated articles. The WG members will use these feedbacks when preparing the BEF-1 final report in 2020.

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# 216 **7.2 BPRS Training for Trainers 2019**



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# 218 **7.2.1 WG progress report**219

The WG Chair informed the plenary that the preparation of the second training for national inspectors under the umbrella of the BPRS is proceeding as per the Activity Plan. The scope of the training event will be online sales of biocides and BPR border line issues. The final agenda of the event was adopted via written procedure by the BPRS.

The BPRS members already nominated one physical trainee per country to be present at the event at ECHA. The Chair of the WG acknowledged that the complexity of the topic together with the difficulties in interpreting the BPR led the WG members to prepare medium level training contents. Nominated trainees should have indeed medium knowledge of the BPR. Part of the training event will be web-streamed for remote attendees.

The WG members are currently preparing the materials to be delivered in the training event (presentations and case studies for the break-out group sessions). The training will be also characterized by a joint session with the 'Forum WG Training for Trainers 2019' which is also focused on e-commerce. The topic of the joint session is the methodology for control of internet sales.

# 2367.3 Implementation of Interact BPR-NEA237

# 238 **7.3.1 WG progress report**

A Forum Secretariat representative informed the plenary about the review of data and functional requirements for biocidal products to be included in the Interact portal for BPR-NEA. The revised requirements were provided to the IT contractor for further analysis. As per earlier decision, no information on active substances will be showed in the final tool. The activities of the WG will continue for the rest of 2019, in view of the release of the new platform for the NEAs in 2020. An update on the work and timeline will be provided at the next plenary meeting.

# 248 **7.4 REACH-EN-FORCE-6 on Classification and Labelling – BPR module**

# 250 **7.4.1 WG progress report**251

A representative of Forum Secretariat informed the plenary about the progress of the REF-6 project on classification and labelling of mixtures. The reporting phase is ongoing and the WG members are analysing the data collected by the NCs with reference to the BPR module of the project. The final Project Report will be delivered towards the end of the 2019.

# 258 **7.5 REF-8 on online sale – BPR module**

# 259260 **7.5.1 WG progress report**

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A BPRS member of the Forum WG informed the plenary about the progress of the REF-8 project. The joint Forum/BPRS WG was tasked to develop the manual which contains a common methodology for the inspections of products sold online for the enforcement of CLP, REACH and BPR.

The work is divided into four subgroups: 'CLP', 'REACH', 'BPR' and 'Methodology' that are currently preparing the manual elements and the respective questionnaire. The BPR module will target biocidal products made available through on-line sales (both authorised and available under transitional measures), and advertising provisions.

The Forum and BPRS members, together with the NCs for the REF-8, are invited to submit comments on the draft manual from the end of June until middle of August.



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The speaker informed the plenary that the training for the National Coordinators (NCs) of the REF-8 will take place on 3 October 2019, back-to-back with the "Training for trainers (TfT) 2019".

# 277 **7.6 Forum/BPRS WG on Reporting**278

# 279 **7.6.1 WG progress report**

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A representative of the Forum Secretariat informed the plenary about the progress report
 submitted to the BPRS members by the WG.

The draft reporting template elaborated by the WG is now under consultation by the Forum and CARACAL. Action has not yet started on the annual report on the PIC template.

The BPRS agreed to consider the feasibility of annual reporting on national BPR enforcement activities with the view of potentially joining the annual reporting pilot now scheduled only for REACH and CLP.

The annual BPR enforcement reporting template would be prepared on the basis of the Art 65(3) report that the MSs need to submit to the COM every five years.

A follow-up discussion on the matter will take place at the next BPRS plenary meeting.

#### 291 292

# **Item 8 – National enforcement policies / Cooperation with other**

# 293 294 8.1 The case of toilet disinfectants: change in formulation of biocidal products 295

296 The Irish BPRS member informed the plenary about the ongoing case of toilet disinfectant 297 in his country. A toilet disinfectant was identified on inspection as having no approval 298 number or active substance information on the label. The retailer was instructed to remove 299 the product from sale and inform their supplier, the notification holder of the product, that 300 the product needed to be labelled in accordance with the Art 69 of the BPR prior to 301 returning to sale. On further investigation it was discovered that the retailer, acting as the 302 marketing company for their own-brand biocidal products, was tendering on an annual 303 basis for a toilet disinfectants, floor cleaners, wipes etc. A number of manufacturers 304 submitted tenders and were accepted to supply the toilet disinfectant under the own-brand 305 product name and branding of the retailer. However, each manufacturer supplied a 306 different formulation containing different active substances for the toilet disinfectant. 307 Consequently, two different toilet disinfectant formulations were available under the same 308 product name and branding. Both formulators had valid notifications and had submitted a 309 trade name with slight differences in the order of the words, so it was not picked up on 310 application that the product trade names were identical. Both applications submitted had 311 identical label which meant the trade name on the register was different to the trade name 312 on the label. The labels did not identify the notification holder, only the marketing company 313 which was the retailer, it was not clear what active substance was in the product. On 314 further investigation, the same situation was identified with all their biocidal product range.

315

316 The retailer was instructed to remove all biocidal product from sale until the issues were 317 rectified. Following meetings with the retailer to expand on the requirements on the BPR, 318 it was explained that their business model of tendering for a toilet disinfectant, or floor 319 disinfectant did not work with the BPR. They would need to become the notification holder 320 of the product and issue a tender to manufacture a specific formulation and identify all the 321 formulators in the notification, or they would need to pick one company, allow them to 322 become notification holder for the own-brand trade name and just purchase the product 323 from this formulator. The company was informed about the changes coming when the 324 active substance is approved, and the time taken to generate a dossier, and have it 325 evaluated. Annual tenders for a disinfectant would not work in a regulated market



326 especially after the date of approval as they would have a market freeze until authorisation 327 for the different products was complete. The Irish NEA also informed them that it is 328 essential that there is full traceability of the products and that on inspection the NEA must 329 be able to identify the product to determine the legal status of the product. If the NEA 330 cannot identify the product, it will be deemed non-compliant. The retailer whom has stores 331 across the EU has now rectified the situation in Ireland, they have chosen one company 332 to act as notification holder and revoked the other notifications.

- The speaker finally wanted to make the BPRS aware that this situation is most likely happening also in other member state.
- 335

# 8.2 The concentration of active substances or how much DEET indeed? - A case study 338

The Swiss BPRS member shared with the plenary the outcome of an enforcement project related to the active substance *N*,*N*-*Diethyl-meta-toluamide* (DEET) that was performed in his country in 2017/2018.

- 342 The project involved laboratory analysis in order to identify and establish the concentration 343 of DEET in several biocidal products commercialised in Switzerland as repellents.
- 344 The main outcome of the project highlighted an average concentration of DEET generally 345 below the content indicated in the authorisations of the concerned products.
- 346 The repellents containing DEET were also examined to establish any deviation among 347 different batches of identical products. The analysis didn't detect any significant deviation.
- Worth noticing that the analysis of different types of biocidal products detected a greater variation of content compare to repellents. This is probably related to the manufacturers of DEET-repellents, which are generally companies with a pharmaceutical background using accurate methods and are working under GMP-conditions.
- The speaker also mentioned that many manufacturers had problems in transposing the labelling elements included in the concerned authorisations in the actual repellents placed on the market. For example, only 50% of the special conditions as RMMs were transposed correctly.
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Finally, the speaker concluded the presentation highlighting the urgent need to complete the review program of existing active substances in order to have the same conditions and authorisations for all biocidal products currently on the EU market.

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# 361 Item 9 – Any Other Business

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# **9.1 Professional users training: result of the survey – IT BPRS member**

At the BPRS-7 the Italian BPRS member delivered a presentation concerning the importance of and need for trainings for industrial or professional users of biocidal products. The BPRS members were invited to provide to the Italian member information on the professional trainings organised in their countries; on certified sale points; and on national rules that defined the use of drones for the application of chemicals at professional level.

At the BPRS-8 the Italian member presented the results of the survey, and was tasked to
 share them via email to the BPRS members.

# 374 9.2 Practises on the enforcement of biocides nanomaterial: result of the survey 375 - French BPRS member 376

At the BPRS-7 the French member asked the BPRS to share the practises that currently are in place in their countries on the enforcement of nanomaterials, for both biocidal



379 products and treated articles. In the coming months the French NEA will start investigating 380 nanomaterials included in products and articles currently placed on the market.

381 Since no reply was received so far, the speaker remarked the need of feedbacks form the 382 BPRS members. The topic will be followed up at the next BPRS plenary meeting, if needed.

# 384 **9.3** Austrian request - Availability of information on applications for Union 385 Authorisations to the NEAs

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387 The Austrian member raised a question to the BPRS on the availability of information on 388 applications for Union Authorisations to NEAs, as long as the new tool called 'Interact BPR' 389 is not available vet to the enforcement authorities. These data indeed are currently 390 available only in R4BP 3 to which NEAs do not have direct access (while their related 391 Competent Authorities do). To check for a potential application for Union Authorisations, 392 which no authorisation number can be clearly identified, the AT NEA needs to inquire the 393 related Competent Authority to investigate the case in R4BP 3. The speaker mentioned 394 that potentially any biocidal product can be subjected to a Union Authorisation application. 395 After a brief discussion on the practises in place in different NEAs, the BPRS members 396 were asked to provide feedbacks on whether the access to those data appears to be 397 problematic during their routine inspections.

398 In case the unavailability of this information to NEAs become clearly a conundrum, the 399 BPRS could request ECHA Secretariat to temporarily help by providing a monthly list of 400 Union Authorisation applications.

401 The topic will be followed up at the next BPRS plenary meeting by the AT member in 402 cooperation with the Forum secretariat.



# **II. MAIN CONCLUSIONS & ACTION POINTS -** Adopted at the BPRS-8

(Public version)

| Agenda point   | Conclusions / decisions / minority opinions  | Action requested after the meeting   |
|--|--|--|
| Item 1- Welcome an   | d introduction   |  |
| 1.1 Opening by the Chair of the BPRS   |  |  |
| 1.2 Introduction of the new HoU of A2  |  |  |
| 1.3 Adoption of the Agenda   |  |  |
| 1.4 Declarations of<br>conflict of interest<br>with regard to<br>agenda items                |  |  |
| 1.5 State of play with<br>action points from<br>BPRS-6                                       |  | BPRS members interested in<br>linkage of the ECHA<br>dissemination website to<br>national IT systems are<br>invited to inform ECHA<br>Secretariat about the specific<br>requirements by 20 August. |
| 1.6 Report of the<br>written procedures<br>and other issues<br>between BPRS-6 and<br>BPRS-7  |  |  |
| Item 2 - Address by  | ECHA Deputy ED- Mr Jukka Malm  |  |
|  | d cooperation with the Forum   |  |
| 3.1 Updates from<br>Forum-33   | BPRS mandated the AT Forum member to represent it at the meetings of the ADCO chairs group.                          | <b>Forum-S</b> to expand the scope of the mandate of Forum representatives to the Commissions WGs to cover also BPRS   |
|  | BPRS agreed that the LU Forum<br>member will represent BPRS at the<br>meetings of the ICSMS WG of the<br>Commission. |  |
| 3.2 Update from the<br>cooperation between<br>BPRS and BPC on risk<br>management<br>measures |  | <b>Forum-S</b> will launch the consultation of risk mitigation measures with the BPRS, after the list has been approved by the BPC.  |
| Item 4 – Debriefing  | of the meeting with ECHA Director  |  |
|  |  | <b>Forum-S</b> will prepare the list<br>of BPR related topics that<br>were discussed with ECHA<br>Directors for the BPRS-9<br>invitation.  |



| Agenda point   | Conclusions / decisions / minority opinions | Action requested after the meeting   |
|--|---|--|
| Item 5 – Practical is                                      | sues for enforcement                        |  |
| 5.1 Items raised by  |   | Forum-S will draft the new   |
| the BPRS/ECHA/COM  |   | questions and conclusion for   |
| , ,  |   | practical issue 5.1 and send   |
|  |   | it for consultation to BPRS.   |
| Item 6 - Updates on  | relevant developments by the Eur            |  |
| 6.1 General updates<br>on the BPR provisions<br>by the COM |   | <b>BPRS</b> members are invited<br>to suggest subjects they<br>wish to be informed by the  |
| by the com   |   | COM in future plenary meetings.  |
|  |   | <b>COM</b> is invited to investigate<br>the impact of the regulation<br>2019/515 on mutual |
|  |   | recognition of goods on the<br>BPR mutual recognition<br>mechanism and inform the          |
|  |   | BPRS at the next plenary meeting.  |
| Item 7 – BPRS  |   |  |
| enforcement  |   |  |
| 7.1 First BPR  |   |  |
| enforcement project,<br>BEF-1                              |   |  |
| 7.1.1 WG progress  |   | BPRS members and the   |
| report   |   | NCs are invited to send any  |
|  |   | reflections or observations  |
|  |   | coming from the experience   |
|  |   | of operational phase of BEF-   |
|  |   | 1 until February 2020  |
|  |   | WG BEF-1 will use this   |
|  |   | feedback when preparing the BEF-1 report.  |
| 7.1.2 Debriefing from                                      |   | WG BEF-1 will elaborate the  |
| the BEF-1 workshop   |   | record of the BEF-1  |
|  |   | workshop including the   |
|  |   | discussions on borderline  |
|  |   | cases by mid-September 2019  |
| 7.1.3 Mandate  | The BPRS reviewed the mandate.              |  |
| amendment  |   |  |
| 7.2 BPR Training for Trainers 2019                         |   |  |
| 7.2.1 WG progress  |   | BPRS members who didn't  |
| report   |   | nominate any trainee (AT,  |
|  |   | BG, CZ, DE, EL, FR, HR, IE,  |
|  |   | IS, IT, LI, LT, MT, NL and PT)   |
|  |   | are invited to do so by 5 July   |
|  |   | at the latest.   |



| Agenda point                                    | Conclusions / decisions /          | Action requested after   |
|---|------------------------------------|--|
|   | minority opinions                  | the meeting  |
| 7.2.2 Mandate<br>amendment                      | The BPRS reviewed the mandate.     |  |
| 7.3   |                                    |  |
| Implementation of<br>Interact BPR-NEA           |                                    |  |
| 7.3.1 WG progress                               |                                    | Forum-S will schedule the  |
| report  |                                    | demonstration of Interact collaboration platform at future BPRS plenary. |
| 7.3.2 Mandate amendment                         | The BPRS reviewed the mandate.     |  |
| 7.4 REACH-EN-                                   |                                    |  |
| FORCE-6 on                                      |                                    |  |
| Classification and<br>Labelling                 |                                    |  |
| 7.4.1 WG progress                               |                                    |  |
| report  |                                    |  |
| 7.4.2 Mandate                                   | The BPRS reviewed the mandate.     |  |
| amendment                                       |                                    |  |
| 7.5 REACH-EN-<br>FORCE-8 on Online              |                                    |  |
| sales   |                                    |  |
| 7.5.1 WG progress                               |                                    |  |
| report  |                                    |  |
| 7.5.2 Mandate                                   | The BPRS reviewed the mandate.     |  |
| amendment                                       |                                    |  |
| 7.6 Forum WG on                                 |                                    |  |
| <b>Reporting</b><br>7.6.1 WG progress           |                                    |  |
| 7.6.1 WG progress report                        |                                    |  |
| 7.6.2 Mandate                                   | The BPRS reviewed the mandate.     |  |
| amendment                                       |                                    |  |
|   | forcement policies / cooperation v |  |
| 8.1 The case of toilet                          |                                    | IE BPRS member will send   |
| disinfectants: change                           |                                    | the information about the  |
| in formulation of                               |                                    | case by email to the Forum-  |
| biocidal products                               |                                    | s by 28 June.  |
|   |                                    | <b>Forum-S</b> will distribute it to the BPRS members by 5 July.         |
| 8.2 The concentration                           |                                    |  |
| of active substances                            |                                    |  |
| or how much DEET                                |                                    |  |
| indeed? – A case                                |                                    |  |
| study   | Rueineee                           |  |
| <b>Item 9 – Any Other I</b><br>9.1 Training for | Business                           | IT BPRS member to  |
| 9.1 Training for professional users of          |                                    | <b>IT BPRS member</b> to distribute the results of the                   |
| biocidal products:                              |                                    | survey prepared by the IT  |
| outcome of the                                  |                                    | BPRS member by 28 June   |
| survey  |                                    |  |



| Agenda point  | Conclusions / decisions / minority opinions | Action requested after the meeting  |
|---|---|---|
| 9.2 Practises on the<br>enforcement of<br>biocides<br>nanomaterial:<br>outcome of the<br>survey |   | <b>FR BPRS member</b> is invited<br>to remind the BPRS<br>members to send in the<br>information requested at<br>BPRS-7  |
| 9.3 Any Other<br>Business   |   | <b>BPRS members</b> are invited<br>to provide feedback on<br>whether the NEAs find it<br>challenging to access<br>information on applications<br>for Union Authorisations by<br>20 August |
|   |   | <b>Forum-S</b> will examine the feedback and if clear need is apparent, will investigate if provision of such data is possible before the release of Interact BPR NEA.                    |
| Item 10 – Adoption of conclusions and action points   |   |   |



# III. List of attendees of the BPRS-8

# **BPRS** members

|    | Country | Name               |
|----|---------|--------------------|
| 1  | AT      | ANWANDER Eugen     |
| 2  | BE      | DE VOS Helmut      |
| 3  | BG      | HRISTOVA Viktoriya |
| 4  | СН      | BURGY Heribert     |
| 5  | CY      | GAVRIEL Alexandros |
| 6  | CZ      | JAROLIM Oldrich    |
| 7  | DK      | HANSEN Lise Bach   |
| 8  | EE      | LINNO Annemari     |
| 9  | ES      | VAZQUEZ Margarita  |
| 10 | FI      | KARNANI Paivi      |
| 11 | HU      | NEMET Balazs       |
| 12 | IE      | MURPHY Brian       |
| 13 | IT      | RAVAIOLI Francesca |
| 14 | LT      | HAKAITE Palmira    |
| 15 | LU      | HERMES Joe         |
| 16 | LV      | ELFERTE Sintija    |
| 17 | NL      | DE BOER Jabik      |
| 18 | NO      | SKARGARD Cathrine  |
| 19 | PL      | PISAREK Dominik    |
| 20 | RO      | CIRLAN Cristiana   |
| 21 | SE      | KARLSSON Jenny     |
| 22 | SI      | NOVAK Vesna        |
| 23 | SK      | POCAROVSKA Miriam  |
| 24 | UK      | POTTS Mike         |

# **Invited Experts**

|    | Country | Name             |
|----|---------|------------------|
| 25 | DE      | SCHROETER Meike  |
| 26 | FR      | TCHANAKIAN Fiona |
| 27 | PT      | DIAS Maria       |

# **European Commission representative**

|    | Country  | Name           |
|----|----------|----------------|
| 28 | DG SANTE | NEGULICI Ligia |



# Advisers

|    | Country | Name              |
|----|---------|-------------------|
| 29 | DE      | WURSTHORN Sibylle |
| 30 | DK      | SKALS Dorrit      |
| 31 | UK      | BISHOP Richard    |

# **ECHA's Forum Secretariat Staff**

|    | ECHA                  | Unit                    |
|----|-----------------------|-------------------------|
| 1  | ALBERTO Joana         | Support and Enforcement |
| 2  | ANNYS Erwin           | Support and Enforcement |
| 3  | BARANSKI Maciej       | Support and Enforcement |
| 4  | CALVO TOLEDO Pablo    | Support and Enforcement |
| 5  | FRONTINI Ales         | Support and Enforcement |
| 6  | KRIMIANIOTIS Georgios | Support and Enforcement |
| 7  | MATEUS Tania          | Support and Enforcement |
| 8  | NIKULA Terhi          | Support and Enforcement |
| 9  | TECCE Nicola          | Support and Enforcement |
| 10 | TLOCZEK Magdalena     | Support and Enforcement |
| 11 | TUOMAINEN Anita       | Support and Enforcement |



# **IV. List of Annexes**

Annex 1. Final agenda of BPRS-8 (as adopted at the plenary)

Annex 2. List of mandates of BPRS WGs/Forum WGs

- 2 a. BPRS WG First BPR enforcement project BEF-1
- 2 b. BPRS WG Training for enforcement trainers 2019
- 2 c. Forum/BPRS WG REACH-EN-FORCE-6 (BPR module)
- 2 d. BPRS WG PD-NEA (BPR)
- 2 e. Forum/BPRS WG REF-8 internet sale (BPR module)
- 2 f. Forum WG Reporting

Annex 3. Final agenda of the BEF-1 workshop



# Annex 1. Final agenda of BPRS-8 (as adopted at the plenary)

# European Chemicals Agency - Helsinki, Finland

# 20 June 2019 from 09:00 to 17:00

# Item 1 – Welcome and Introduction

09:00-09:30

- 1.1 Opening by the Chair of the BPRS BPRS Chair
- 1.2 Introduction of the new HoU of A2
- 1.3 Adoption of the Agenda BPRS Chair
- 1.4 Declarations of conflict of interest with regard to agenda items *BPRS Chair*
- 1.5 State of play with action points from BPRS-7 ECHA Forum Secretariat
- 1.6 Report of the written procedures and other issues between BPRS-7 and BPRS-8 *BPRS Chair*

# For information/adoption

ECHA/BPRS-8/2019/1.5 ECHA/BPRS-8/2019/1.6

Item 2 – Address by ECHA Deputy ED– Mr Jukka Malm 09:30-09:40

# For information

**Item 3 – Updates and cooperation with the Forum** 09:40-10:00

- 3.1 Updates from Forum-33 (15') Forum Chair/Vice Chair/Forum member
- 3.2 Update from the cooperation between BPRS and BPC on risk management measures (5') *BPC Chair*

# For information

Item 4 – Debriefing of the meeting with ECHA10:00-10:10Directors by BPRS Chair10:00-10:10

For information

| Item 5 – Practical issues for enforcement | 10:10-11:00 |
|---|-------------|
|---|-------------|

5.1 Items raised by the BPRS/ECHA/COM (list of practical issues is prepared independently from the agenda) - *ECHA Forum Secretariat* 



*For discussion/adoption* ECHA/BPRS-8/2019/5.1

# Coffee break 30'

# Item 6 – Updates on relevant developments by the 11:30-12:15 European Commission

6.1 General updates on the BPR provisions by the COM (45')

# For information/discussion

# Lunch break 60'

Item 7 – BPRS enforcement activities

13:15-14:50

- 7.1 First BPR enforcement project, BEF-1 (15')
  - 7.1.1 WG progress report WG Chair
  - 7.1.2 Debriefing from the BEF-1 workshop WG Chair
  - 7.1.3 Mandate amendment ECHA Forum Secretariat
- 7.2 BPR Training for Trainers 2019 (10')
  - 7.2.1 WG progress report WG Chair
  - 7.2.2 Mandate amendment ECHA Forum Secretariat
- 7.3 Implementation of Interact BPR-NEA (BPR) (25')
  - 7.3.1 WG progress report WG Chair
  - 7.3.2 Mandate amendment ECHA Forum Secretariat
- 7.4 REACH-EN-FORCE-6 on Classification and Labelling (BPR) (20')
  - 7.4.1 WG progress report- WG member
  - 7.4.2 Mandate amendment ECHA Forum Secretariat
- 7.5 REACH-EN-FORCE-8 on Online sales (BPR) (10')
  - 7.5.1 WG progress report BPRS Chair
  - 7.5.2 Mandate amendment ECHA Forum Secretariat
- 7.6 Forum WG on Reporting (BPR) (15')
  - 7.6.1 WG progress report BPRS Chair
- 7.6.2 Mandate amendment ECHA Forum Secretariat

# For information/discussion/adoption

ECHA/BPRS-8/2019/7.1.1 ECHA/BPRS-8/2019/7.2.1 ECHA/BPRS-8/2019/7.3.1 ECHA/BPRS-8/2019/7.4.1 ECHA/BPRS-8/2019/7.5.1 ECHA/BPRS-8/2019/7.6.1



Coffee break 30'

# Item 8 – National enforcement policies / cooperation 15:20-16:00 with other networks

- 8.1 The case of toilet disinfectants: change in formulation of biocidal products (20') *IE BPRS member*
- 8.2 The concentration of active substances or how much DEET indeed? A case study (20') CH BPRS member

# For information/discussion

| Item 9 – Any Other Business | 16:00-16:45 |
|-----------------------------|-------------|
| Item 9 – Any Other Business | 16:00-16:4  |

- 9.1 Training for professional users of biocidal products: outcome of the survey *IT BPRS member* (10')
- 9.2 Practises on the enforcement of biocides nanomaterial: outcome of the survey *FR BPRS member* (10')
- 9.3 Any Other Business

# For information/discussion

| Them 10 Adaption of conclusions and action points   | 16:45-16:55 |
|---|-------------|
| Item 10 – Adoption of conclusions and action points | 10.45-10.55 |

**End of Meeting** 

17:00



# Annex 2. List of mandates of BPRS WGs/Forum WGs

2 a. BPRS WG - First BPR enforcement project – BEF-1 "BPRS BEF-1" BPRS Working Group "BPR enforcement project on treated articles" (Mandate adopted at BPRS-8)

## Composition

Chair: Jenny KARLSSON (SE)

Vice Chair: Jabik DE BOER (NL)

#### **BPRS Members/Alternates:**

- Francesca RAVAIOLI (IT)
- Marios ADAMIDES (CY)
- Heribert BURGY (CH)
- Marianne BRAAM (NL)

#### **Invited Experts**

- Karin PFAFF (DE)
- Nadine GRISEL (CH)
- Serge PICCOLO (FR)
- 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

#### 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: Q1 2020
- Questionnaire to be run after the BPRS-3
  BEF-1 workshop in June 2019



## 2 b. BPRS WG - Training for enforcement trainers 2019 "BPRS Train the trainers 2019"

## **BPRS Working Group**

#### "Training for enforcement trainers 2019"

(Mandate adopted at BPRS-8) Composition

Chair: Dominik PISAREK (PL)

## **BPRS Members/Alternates:**

- Francesca RAVAIOLI (IT)
- Heribert BURGY (CH)

#### **Invited Experts:**

- Nils MANEGOLDd (DE)
- Markus KLAR (SE)
- Nadine GRISEL (ĆH)
- Lena GRUHN (DE)

## ECHA

- Nicola TECCE

#### **Objective:**

Prepare and deliver the training for trainers on the enforcement of BPR in the fourth quarter of 2019.

### Mandate:

- 1. Examine the training subjects relevant for enforcement in the fourth quarter of 2018 and prepare the priority topics for agreement by BPRS-7
- 2. Specify the envisaged level of the content of the training
- 3. Prepare materials necessary for the training such as presentations or documents
- 4. Cooperation with the Forum WG TfT 2019 and REF-8 on online sales
- 5. Actively conduct the training event with support from other BPRS members, ECHA and COM and other experts in specific topics as necessary.
- 6. Collect, summarise and evaluate the recommendations and reactions of participants

#### Timeline:

- By the BPRS-7: conclude on list of subjects and prioritisation, adopt the agenda of the training event
- BPRS-9: final report



#### 2 c. BPRS WG – Interact (BPR-NEA) "Interact BPR-NEA" BPRS Working Group "Implementation of Interact BPR NEA" (Mandate adopted at BPPS-8)

(Mandate adopted at BPRS-8)

## Composition

Chair: Eugen ANWANDER (AT)

#### **BPRS Members/Alternates:**

- Francesca RAVAIOLI (IT)
- Brigitte EDER (AT)

#### **Invited Experts:**

- Natalija UMBRASIENE (LT)
- Jurgen SCHMID (DE)

#### **ECHA**

- Jolanta STASKO (D2)
- 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-10 (Q1 2020)



## 2 d. Forum/BPRS WG - REACH-EN-FORCE-6 (BPR module) "REF-6" Forum Working Group Work Package A.1 "Coordinated enforcement project REACH-EN-FORCE-6"

(Mandate adopted at Forum-33 and BPRS-8)

### Composition:

Chair: Henrik HEDLUND (SE)

### Forum Members and Alternates

- Gro HAGEN (NO)
- Elena ZIDAROVA (BG)
- Dimitrios CHATZIANTINOU (EL)
- Graca BRAVO (PT)
- Žilvinas UŽOMECKAS (LT)
- Markus MAKI (FI)

#### **Invited Experts**

- Petra SCHLAG (DE)
- Panagiota SKAFIDA (EL)
- Adhemar ROG (NL)
- Harm VOERMAN (NL)

#### **BPRS Members and Experts**

- Viktoriya HRISTOVA (BG)
- Anna MASLARSKA (BG)

#### ECHA

- Outi TUNNELA (B4)
- Ales FRONTINI
- Anita TUOMAINEN

#### **Objective:**

- conceive and manage the sixth major Forum enforcement project REF-6

#### Mandate:

- 1. Management of the Operational phase
- 2. Management the Reporting phase: Follow-up operational phase, collect the results and draft project evaluation
- 3. Elaborate tips and hints for inspectors based on the relevant outcomes from the project
- 4. Include biocides in the scope of the project in collaboration with the appointed BPR experts
- 5. Define the scope of enforcement activities under Art 45 and Annex VIII of CLP
- 6. Address in the manual the issue of mechanical compression strength of the LLDCs



#### 2 e. Forum/BPRS WG - REF-8 internet sale (BPR module) "REF-8"

Forum Working Group <u>Work Package A.1</u> "Coordinated enforcement project REACH-EN-FORCE-8" (Mandate adopted at Forum-33 and BPRS-8)

## **Composition:**

Chair: Karin RUMAR (SE)

#### Forum Members and Alternates

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

#### **Invited Experts**

- Kevin BUCKLEY (IE)
- Sara YASSINE (DK)
- Timea TARNOCZAI (HU)
- Jurgita BALCIUNIENE (LT)
- Ingrida STULGIENE (LT)
- Lotta KAILA (FI)
- Olivier COUTURAUD (FR)
- Marilin LUTSOJA (EE)

#### **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)
- Fiona TCHANAKIAN (FR) (BPR expert)
- Anne HORN (DE) (BPR expert)

#### **ECHA**

- Tania MATEUS
- Ales 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:

- 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

#### 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

#### 2 f. Forum WG – MS Reporting "MS reporting"

# Forum Working Group

### "MS Reporting"

(Mandate created at Forum-33 and BPRS-8)

## **Composition:**

- Chair: Sinead MCMICKAN (IE)

## Forum Members/Alternates

- Katja VOM HOFE (DE)
- Michael FAGERLUND (DK)
- Markus MAKI (FI)
- Elenza ZIDAROVA (BG)
- Emily RASOOLY (FR)

## **BPRS Members/Alternates**

- Francesca RAVAIOLI (IT)
- Annemari LINNO (EE)
- Dominik PISAREK (PL)

#### **Invited Experts**

- Andrea MAYER-FIGGE (DE)
- Monika AVIZIENE (LT)

#### Commission

- Ligia NEGULICI (DG SANTE)

#### **ECHA**

- Maciej BARANSKI
- Ales 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

Timeline: Forum-35 (March 2020)



# Annex 3. Final agenda of the BPRS BEF-1 workshop

# Date: 19 June 2019 from 15:00 until 18:00

Place: ECHA Library room

**Chair:** Jenny Karlsson (SE BPRS member)

| Time  | Item | Subject   |  |
|-------|------|---|--|
| 14:30 | 1.0  | Arrival of participants and registration  |  |
| 15:00 | 2.0  | Opening of the event and details on the workshop  |  |
| 15:15 | 3.0  | Break-out groups discussion – <b>First session</b>  |  |
|       | 3.1  | <ul> <li>State-of play with national inspections</li> <li>Communication with national stakeholders</li> <li>Interactions among NEAs while enforcing treated articles</li> </ul> |  |
|       | 3.2  | <ul> <li>Interpretation of the Manual for the BEF-1</li> <li>How to use COM and CA documents</li> <li>Article 94 list</li> </ul>  |  |
|       | 3.3  | <ul><li>Borderline/scope issues</li><li>Implementation of Article 3(3) decisions</li></ul>  |  |
| 16:15 | 4.0  | Coffee break  |  |
| 16:30 | 5.0  | Break-out group discussion - Second session   |  |
| 17:30 | 6.0  | Debriefing by the break-out groups moderators   |  |
| 18:00 | 7.0  | End of the workshop and reception offered by ECHA   |  |