29 September 2016

BPC-M-16-2016

Minutes of the 16th meeting of the Biocidal Products Committee (BPC)

14 – 16 June 2016

Part I - Summary Record of the Proceedings

1. Welcome and apologies

The Chairman of the Biocidal Products Committee (BPC) welcomed the participants to the 16th BPC meeting and informed the meeting that no changes occurred recently in the BPC membership.

To continue, the Chairman informed the BPC members of the participation of 26 members, including five alternates.

Fifteen advisers, one invited expert and two representatives from accredited stakeholder organisations (ASOs) were present at the meeting. Two representatives from the European Commission also attended the meeting. Apologies were received from two BPC members and two ASO representatives.

Applicants were present for their specific substances and the details are provided in the summary record of the discussion for the substances and in Part III of the minutes.

2. Agreement of the agenda

The Chairman introduced the final draft agenda (BPC-A-16-2015_rev2) and mentioned the addition of one item in the AOB section: "Data received for copper, granulated after active substance approval".

The Chairman also mentioned that the document "Public consultation on substances meeting the exclusion or substitution criteria" was finalised at the last CA meeting and published by the Commission. This document has important consequences for the activities of the BPC for active substances being candidates for substitution. The SECR will inform the BPC at the next meeting on their ideas on how to implement this document.

To follow, the Chairman invited then any additional items. No additional item was suggested.

The agenda was then adopted. The final version of the agenda will be uploaded to the BPC CIRCABC IG as part of the meeting minutes.

The Chairman informed the meeting participants that the meeting would be recorded for the purpose of the minutes and that the recording would be destroyed after the agreement of the minutes.

The list of meeting documents and the final version of the agenda are included in Part IV of the minutes.

3. Declarations of potential conflicts of interest to the agenda

The Chairman invited BPC members, alternates and advisers to declare any potential conflict of interest in relation to the agreed agenda. None was declared.

4. Agreement of the draft minutes and review of actions arising from BPC-15

The revised draft minutes from BPC-15 (BPC-M-15-2016), incorporating the comments received from members, were agreed.

Under the follow-up of the actions arising from BPC-15, the Chairman informed the meeting that the SECR amended the opinion and Assessment Report templates and published them on CIRCABC. It was mentioned that the templates have been combined, allowing their use for new and existing active substances. BPC members were also informed that the SECR amended the "Manual on preparing the BPC opinion" and finalised the document on data received after the approval of the active substance and published both these documents on CIRCABC.

The Chairman indicated that the timelines for the next process flows, based on the agreement reached at BPC-15 on revising the working procedure for active substance approval, have been prepared by SECR and published on CIRCABC and on the ECHA website. Checklists for the accordance checks have also been developed by ECHA and have been presented at the last Working Group meetings. These checklists should be used from now on.

On the topic concerning data received after the approval for S-methoprene and cyproconazole, the Chairman informed the meeting that no comments were received during the commenting phase. Therefore the eCA can finalise the documents.

To follow, the Chairman informed the members that the SECR did not manage to proceed with the projects on developing the processes for active substance approval renewal and Annex I inclusion, where the intention was to open two Newsgroups containing a document developed by the SECR on questions to be asked to MSCAs on these processes. It is foreseen that this will be done before the next BPC meeting.

Actions:

- **SECR:** to upload the agreed minutes from BPC-15 to the BPC CIRCABC IG and to the ECHA website after the meeting.

5. Administrative issues

5.1 Housekeeping issues

The SECR highlighted the key aspects of the housekeeping rules including the safety and security rules.

5.2 Administrative updates and report from other ECHA bodies

The Chairman introduced document BPC-16-2016-01 covering the administrative updates and the report form the other ECHA Committees, provided to members for information purposes. The Chairman noted that the updates from RAC and SEAC will be provided in the next report, as the meetings of these committees took place at the beginning of June. The document contains the foreseen dates for the BPC meetings in 2017.

5.3 ECHA policy on the prevention and management of conflicts of interest

An overview was presented on the ECHA policy on the prevention and management of conflicts of interest.

5.4 Establishment and mandate for the Ad-hoc Working Group on Micro-organisms (Ad Hoc WG MO)

The Chairman introduced document BPC-16-2016-23, detailing the objectives, scope and output of the dedicated ad-hoc working group on micro-organisms. The Chairman noted that the main reason for the establishment of this working group was the lack of expertise in this field in the permanent working groups. The Chairman clarified that the meetings of the working group will be almost always virtual meetings. In addition, the Chairman clarified that it is foreseen that all technical and scientific aspects of an application for approval will be discussed in the working group, after which the evaluation will directly be discussed by the BPC. The BPC agreed on the establishment of this working group as well as on its mandate. Subsequently, the SECR will now start inviting members.

The Chairman also announced that the commenting period on the Draft Guidance on Estimating Dietary Risk from Transfer of Biocidal Active Substances into Foods – Non-professional Uses will end on 30th of June. BPC members were informed that the draft guidance has been published on the ARTFood webpage with the aim of collecting comments and feedback from MSCAs and applicants. The comments will be reviewed and the draft guidance will be revised accordingly through the ECHA guidance consultation procedure. The Chairman invited the members to submit their MSCA comments through the feedback form embedded in the guidance document.

Actions:

- **SECR** to make the mandate available via CIRCA BC and the ECHA web-site;
- **SECR** to initiate the nomination process for the Ad Hoc WG MO.

6. Work Programme for BPC for 2016 – 2017

6.1. Revised Work Programme 2016-2017

The Chairman presented the revised Work Programme, mentioning that this version is a revised version of the previously disseminated one, following consultations with the MSCAs.

The Chairman noted that the schedule for this year includes fifty opinions for the Review Programme and eight for new active substances (under BPD or BPR). The Chairman expressed the concern that, due to some likely delays concerning some dossiers, the target of fifty opinions per year might not be met. With regard to 2017, the Chairman mentioned that seventy-five opinions for the Review Programme and fifteen opinions for new active substances (under BPD or BPR) are currently scheduled. The Chairman also stated that

some of these evaluations are likely to be delayed and that, if needed, priority will be given to the opinions for the first and second priority list.

Actions:

- **Members**: to send information on any further changes to the Work Programme (WP) to the SECR by 23 June 2016.
- **SECR**: on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.

6.2 Outlook for the second priority list

The Chairman referred to the document containing an overview for the substances on the second priority list and pointed out that a BPC opinion still needs to be adopted for 98 active substance product type combinations. The Chairman went on explaining that for most of them the SECR has received information from the eCA on when they could be scheduled for the WGs and BPC or whether the eCA cannot meet the legal deadline of December 2016. The Chairman then pointed out that for 22 combinations the SECR has not yet received any indication on their planning and he invited the involved BPC members to inform the SECR about their planning.

Actions:

- **Members**: to send information on their planning for the second priority list to the SECR by **15 August 2016**.

7. Applications for approval of active substances

7.1 a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

The Chairman introduced the document mentioning it contained no changes after the previous BPC meeting.

7.1 b) Revision of the working procedure for active substance approval following BPC-15

The Chairman introduce the revised working procedure (version 4.0), which implements the revision of the working procedure agreed at BPC-15 and includes the need for a proposal for the reference specification in the accordance check. The Chairman informed that nowadays ECHA prefers that the draft CAR is submitted by the eCA via the R4BP. This will also be reflected in the relevant steps of the revised working procedure.

Actions:

- **SECR**: to make the revised working procedure available via CIRCA BC and the ECHA web-site.

7.2 Draft BPC opinion on peracetic acid for PT 11 and 12

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The rapporteur introduced the substance and the general issues related to the assessment report (AR) and opinion. There was common agreement with no discussion since the specific points referred to clarifications, text refinement and typo/editorial remarks.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

7.3 – 7.10 General discussion on anticoagulant rodenticides

The Chairman welcomed the applicants for this item. The Chairman noted that the applicants had not objected to the presence of ASOs during the discussion. The session was therefore kept open. A general discussion on the renewal of anticoagulant rodenticides took place.

Article 37

COM clarified when Article 37 can be used for derogation. A "shall" provision indicates condition(s) from which derogation is not possible and which must be applied during product authorisation. For example *"Products shall contain an aversive agent and a dye."* means that products without an aversive agent and/or dye must not be authorised. A "may" provision allows certain product authorisations, however, other Member States may decide to derogate from its authorisation according to Article 37. For example the following specific condition "*Products may be authorised for use in pulse baiting treatments*." would allow in the particular case to grant an authorisation for the use in pulse baiting treatments from which another MS may derogate and not authorise such a use.

Evaluation of data

A discussion will be initiated at the Coordination Group to address stability issues related to shelf life for certain anticoagulant biocidal products.

The need to re-evaluate data during product authorisation and/or potentially at the next renewal was discussed. It was noted that the approach taken for the anticoagulant rodenticides renewal is an exception to normal renewals. Following earlier agreement at the CA and in coordination meetings, for these renewals the existing information was not re-evaluated as the focus was on critical review of the conditions of use of these substances and identifying appropriate risk mitigation methods (RMM).

The BPC agreed that for the current active substance renewal of the anticoagulant rodenticides, analytical methods identified as data gaps at the original active substance approval and monitoring methods for enforcement purposes are required.

It was agreed that dermal absorption should be re-evaluated at product authorisation based on current guidance. It was noted that over 3000 product authorisation renewals are expected for rodenticides. Pragmatism will be needed in applying the EFSA guidance, especially with respect to read-across between different formulations. The SECR raised that re-evaluation might lead to no longer accepting existing studies and, as a consequence, new studies might need to be requested or default values, up to 75% may need to be used. Due to time constraints new studies cannot be carried out. It was agreed that dermal absorption of rodenticide products will be taken up at the next Coordination Group (CG) meeting and the CG may initiate discussions at the Human Health Working Group to assist harmonisation of rodenticide product evaluations. A member noted that if a Working Group discussion is taking place, the earlier Technical Meeting agreement related to a specific bromadiolone formulation should also be considered.

It was discussed if the PBT status needs to be determined and further studies may be requested later. The Chair emphasised, when considering whether it is necessary to establish the PBT status, including potentially referring anticoagulant rodenticides to the PBT expert group, it must be taken into account that the exclusion criteria are already met and the critical effects are primary and secondary poisoning. A member commented that degradation in soil and formation of metabolites were not evaluated and the Environment WG should discuss whether these points need to be addressed for the next renewal. The Chair noted that the purpose was not to re-evaluate the data and additional data may not affect the conclusions of the evaluation. Another member said that the purpose of the risk assessment is to identify risks to the soil compartment based on understanding the fate and behaviour of the substance. The member referred to a particular case at product authorisation, where a risk for the soil compartment was identified for the open area scenario for a product, leading to restriction of its use to bait boxes. The concern was product and use specific, however the information on the behaviour and fate of the substance is substance related. To follow up, the BPC agreed that a discussion at the Environment Working Group will be initiated on specific requirements for environment for the next rodenticide active substance renewal.

It was agreed that the SECR will initiate a general discussion at the BPC WGs to identify data requirements for renewal, including considering guidance changes becoming available after approval. These data requirements will be relevant for the future active substance renewals. Since anticoagulant rodenticides meet the exclusion criteria, but are at the same time key for rodent control, the BPC and its WGs will need to consider options to derogate from the requirements set for renewals. Some data requirements may not be necessary, as the main concern of primary and secondary poisoning as well as classification of reproductive toxicity will not change and therefore some data may not influence the required RMM or the conclusion. The reason for asking for data will need to be considered; whether it will be used in comparative assessments to differentiate between substances and whether it would have an impact on the RMMs. A further difference compared to other substances is that for active substances meeting the exclusion criteria the renewal is reviewed after 5 years, in contrast to 15 years for normal renewals.

Section 2.2.3 of the Assessment Report

It was discussed if section 2.2.3 of the assessment reports needs to be harmonised and aligned with the opinions. This section is not harmonised among the assessment reports and may not be fully in line with the overall conclusions of the BPC that is included in the opinions. As it was intended to reflect the views of the respective evaluating CAs and Applicants, it was agreed to keep it in with an explanation on the process and the connection between this section and 2.3 and 2.4 in the opinion.

Generic conditions

The general restriction to ready to use products refers to avoiding concentrated product on the market to prevent the need for dilution by the user.

On the use of contact formulations a detailed discussion took place. The use of tracking powder is prohibited due to increased severity and risk of poisoning from its dusty formulation, difficulty to remove, and its high concentration. Other contact formulations (foams and gels) may be authorised for a restrictive indoor use, only as a last resort and only for use by trained professionals. It was noted that contact formulations may be necessary in places where food is abundant. Contact formulations are not eaten like baits, but attach to the fur/body of the rodent and are ingested during grooming. Rodents will go out of buildings and this will increase the risk of secondary poisoning. The concentration in contact formulations are generally much higher compared to bait formulations.

With respect to authorising second generation anticoagulant rodenticides (SGARs) for contact formulations Member States had diverging opinions. Several MSs opposed the authorisation of SGARs for such use, as the higher potencies combined with higher concentrations will increase primary and secondary poisoning of non-target animals as well as the risk of primary poisoning for children. Even at the same concentration as for bait formulations the risks are elevated. Other MSs argued to leave open the possibility to authorise SGARs as contact formulations, in view of the potential for resistance and the limited number of rodenticides. It was agreed that if a SGAR is authorised, the concentration in contact formulations must not exceed that of other formulations for the particular substance. It was highlighted that Member States may derogate from mutual recognition of SGARs for this use based on Article 37.

With respect to training, considering the nature of anticoagulant rodenticides, there was unanimous agreement that special attention is required for their use. The level of training to be achieved is decided at national level due to the diverging circumstances in the different MSs e.g. the status of farmers. Some MSs commented that trained professionals have less restrictions for the use of rodenticides, therefore in return it should be ensured that they receive appropriate level of training to reduce the risks. There should also be more initiatives for training, in particular in some MSs, to ensure appropriate and sustainable use. Different instruments may be used, training may be organised by industry or by authorities.

Reference was made to the CA guidance, which refers to specific skills for trained professionals. The ASO expert mentioned that EN16 636 and the CEPA certificate lists the competencies considered relevant for a trained professional. According to the ASO expert, in approximately one third of the member states training is compulsory for professionals in order to use the products; in another third, organised training is available but not

compulsory for all professional users; and third of the MSs do not have organised training for such products.

Since training is not related to specific active substances and is a more general issue with specific national considerations, an element to be taken into account at product authorisation referring to the encouragement of training was added.

Conditions for the category "General public":

On the use of tamper resistant bait stations by the general public, it was agreed that the use of refills is not excluded. Some members considered requesting refill packs to be sold together with bait boxes to ensure that refills are not used outside of bait stations. Other members were of the opinion that this measure would hinder achieving waste reduction goals, furthermore this could lead to the general public storing higher quantities of unused baits stations at home. One member noted that there may be other ways to safeguard that refills are used only within bait stations. In Norway, for the general public, SGAR are authorised exclusively in prefilled bait stations for mice –as for bait stations are smaller, however, first generation anticoagulant rodenticides (FGARs), which are less potent compared to SGARs, are also authorised to be used in refillable bait stations for rats and mice.

It was noted that having a window on bait boxes facilitates checking bait consumption, without the need to open the bait-box.

It was noted that in the UK, for non-professional mice control, placing covered baits in places out of the reach of children or pets is also allowed.

Setting a maximum pack size for the general public was discussed in detail. To increase harmonisation among Member States and facilitate mutual recognitions, the maximum pack size was agreed to be a condition supported by the majority of the members. The proposal in the RMM report established by experts that defines the substance and formulation specific maximum quantities of bait per pack was agreed. One member commented that the proposal is comparable to the pack-sizes set by EPA for uses in the U.S. The IND representative considered the calculations in the proposal as incorrect and stated that top up during treatment was also not considered. The IND representative claimed that the proposed pack sizes for non-professionals would be sufficient for a maximum of 1-2 bait points, which would pose a problem in those MSs in which farmers are not considered as professionals. The proposal by industry to have a maximum pack size up to 1.5 kg did not differentiate between SGARs and FGARs, nor did it give explanation on its derivation. The ASO expert estimated that 1.5 kg of bait would be sufficient to kill 10-20 rats. A number of MSs do not differentiate pack sizes based on FGAR/SGAR and a maximum pack size of up to 1.5 kg is generally used. However, a member argued that amateurs may buy more rodenticides than necessary with higher pack-sizes as it is usually cheaper to buy larger quantities. This would be in contrast to the objective of minimising use and avoiding storage of unused packs at home. Moreover, at mutual recognition if the pack sizes are high the harmonisation is expected to be lower as a number of member state may derogate from such authorisation.

It was stated that it would be more appropriate to refer not to maximum pack size but to maximum quantity of bait (as the numbers refer to weight) so that the packaging and bait

station would not be included. In addition, it was stated that it refers to the "overall/total" pack, which may include several smaller packs, where the quantity of bait in this "overall/total" pack shall not be higher than the quantities indicated in the table. The applicants stated that they were not aware of any agreement on the maximum pack size for the general public (or minimum pack size for professionals) from previous meetings.

With reference to mice control, in a number of MSs, for general public, mice control is restricted to in and around buildings. However, applying bait stations around the house increases primary and secondary poisoning of non-target animals. Given the natural behaviour of house mice to stay indoors, it is unlikely that restricting its treatment to indoor applications only will affect its control. The ASO expert also confirmed that house mice live inside buildings as, due to lower temperature, they would not survive outside for longer periods. Thus the BPC agreed to restrict amateur use against mice to indoor use only. A number of member states supported to not specify *Mus musculus* in the provision and keep it more general, as the general public is not able to differentiate at species level. However, for other species with different behaviour (like the yellow necked mice) only indoor control might be insufficient and the use in and around buildings may need to be considered. As these other species may be more relevant in some countries than house mice, reference to house mice in the provision was maintained.

On informing the general public on sustainable use, COM proposed to require two separate leaflets, one providing product specific information related to the use of the product and the other a more general leaflet that would provide information on the hazards and risks of using anticoagulant rodenticides, proposing alternative measures to encourage the reduction of their use and the concepts of sustainable rodent control. The former would be made available by the authorisation holder, whereas the latter would be produced by an umbrella organisation e.g. CEFIC.

Members were concerned that the general public will not read two leaflets; they are more likely to read concise and simple information. The considerable overlap of the information in the two leaflets was also pointed out. Furthermore, given that it is too late for a consumer to consider alternative methods after having already bought the product, there was concern as to who would provide the general leaflet and where and when it would be available to the consumer. If the responsibility for dissemination will be placed on the supplier, at the point of supply, the incentive of the person selling rodenticides to promote alternative, non-chemical methods is also questionable. In general, it was agreed that the necessary information can be transmitted *via* several media from providing a separate leaflet to information on the web-site or on the bait station. Finally, it was agreed that persons making products available on the market shall ensure that the products are accompanied by information on the risks associated with anticoagulant rodenticides in general, measures to limit their use to the minimum necessary and appropriate precautionary steps to be taken, as the leaflet referring to the product specific information is already covered by the provisions in Article 69(2) of the BPR.

On loose bait formulations (grains and pellet) it was stated that the RMM report and workshop concluded that these formulations need to be available for all categories of users, including the general public. One member stated that compared to formulations like pastes or wax blocks, the potential risk for primary and secondary poisoning is higher, as rodents take such baits more easily away from the baiting point. It was proposed to add a condition for the general public stating that such formulations have to be supplied in

sachets or other packaging. Several members mentioned that this is already current practice in their country and one member stated this will also reduce the potential for human exposure. It was decided to add a condition to section 2.3.B.1. with regard to this.

Conditions for the category "Professional users":

It was discussed if professional users shall also be allowed to use covered and protected bait points. It was stated that the RMM report concluded in this line, but at the workshop it was recommended to only allow this for trained professionals. The applicants stated that farmers (not being regarded as trained professionals in some MS) would need such products for treatment of black rats. One member stated such products may be needed around farms, but in those MS farmers are not trained on the use of rodenticides. Based on the opinions expressed by several members, the Chairman concluded that the majority of the meeting recommended to allow the use of covered and protected bait points by trained professionals.

Conditions for the category "Trained professionals":

It was discussed if the use of covered and protected bait points must be restricted to indoor use only. The majority of the meeting stated that outdoor use must be allowed, referring to use in rat burrows, sewers or black rat infestations. One member stated that detailed use instructions for these products can and must be included in the SPC. It was stated that these products can only be used if they provide the same level of protection for non-target species and humans as tamper-resistant bait stations. Following a comment by the applicants that there is a difference between the level of protection for refillable and non-refillable tamper-resistant bait stations, it was concluded to only make reference to tamper-resistant bait stations.

The use by trained professionals in permanent or pulse baiting treatments was then discussed. The meeting supported that pulse baiting treatments shall be restricted to products containing the potent SGARs (brodifacoum, difethialone and flocoumafen). The applicants stated this is the current practice. In addition, it was concluded that the same potent SGARs shall not be authorised for use as a permanent bait. It was clarified that by phrasing the condition as such, this means that products containing these SGARs can still be used for example in the food industry in a long term treatment where permanent baiting is used. However, products containing these SGARs are used here as a kind of "one off" treatment as so-called "resistance breakers". Lastly, it was discussed if products containing FGARs can be used as a permanent bait. It was argued that this may be allowed with the restriction to "sites with a high potential for reinvasion when other control methods have proven insufficient". Some members argued that for these FGARs there is proven resistance therefore the use as a permanent bait should not be allowed, as this type of use would significantly increase the risk of further resistance development. For the latter reason it was decided that all FGARs cannot be used as permanent bait.

Elements to be taken into account for product authorisation

The relation between the adoption of the opinions and the on-going activities of the "Working Party on SPCs for anticoagulant rodenticides" was clarified by the Commission. These activities have been put on hold awaiting the adoption of the opinions. For several of the elements incorporated, a more detailed wording can be elaborated by the Working Party. It was decided to indicate this in the opinions.

The issue of frequency of revisiting the treated areas for the different types of users was discussed. For trained professionals it was concluded that the frequency should be at the discretion of the operator. For the general public and professionals it was concluded that a recommendation on the frequency needs to be included. It was not considered necessary to include a minimum frequency. If available, a reference can be made in the SPC to national codes of good practice.

It was discussed if a minimum pack size for professionals and trained professionals must be introduced: i) as a condition (to be consistent with the maximum size for the general public) or as an element to take into account for product authorisation; ii) which value should be indicated, where 5 kg was proposed. The main concern expressed by some members on introducing a minimum pack size as a condition was that this may lead to waste and disposal issues, as the minimum may be too high for certain professionals, for example farmers or gardeners. On the other hand it was stated by some members that (as the objective is to have clearly separated products in the market for the general public and (trained) professionals to prevent the general public from having access to high quantities of these substances) the window between the maximum for the general public and the minimum for (trained) professionals must be "sufficiently wide". It was argued that the value of 5 kg may be too high, especially considering the SGAR. It was also stated that the value may be too high for farmers, but that occasionally professionals may use products for the general public. Based on the majority opinion of the members, the Chairman concluded to introduce the minimum value of 5 kg as an element for product authorisation.

It was agreed to include the following element: information should be available for professionals as well as non-professionals on non-chemical measures to prevent and control rodent infestations. It was stated that such information should be available separately from the product information in order to enable to inform these user groups beforehand. It was also stated that this is especially aimed at mice control products and that such an element is not required for trained professionals, as it can be assumed they have sufficient knowledge.

It was then discussed if, for products being used in public areas, the areas treated should be marked during the treatment period with a notice. Disadvantages were mentioned by some members (risk of vandalism and being problematic for example for the owner, in case of treatment near supermarkets) while on the other hand it was stated by some members that this is as important and similar to labelling bait boxes with product information. The Chairman concluded to incorporate this element.

Actions:

- **SECR:** to initiate a discussion at the next Coordination Group meeting on information requirements for dermal absorption for the renewal of product authorisation; and on stability issues related to shelf life for certain anticoagulant biocidal products (cereal-based products);
- **SECR:** to initiate a discussion at the Working Group Environment on information requirements with respect to the next renewal of active substance approval;
- **SECR:** to initiate a discussion at the Working Group APCP on information requirements for renewal of active substance approval in general (e.g. analytical methods).

7.3 Draft BPC opinion on chlorophacinone for PT 14

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

With reference to the P criterion it was agreed to discuss this issue at the ENV WG, then all necessary data might be submitted by the next renewal. For the time being chlorophacinone is classified as potentially P.

It was agreed that the LoEP in relation to relevant metabolites will be updated by NL. The discussion on new requirements will take place at ENV WG. The ENV WG will also discuss the need for submission of a water-sediment study and soil simulation study. If applicable, new data will be required by the next renewal.

A general note will be added to the opinion on potential additional data requirements for the next renewal.

The Assessment Report was agreed subject to the changes agreed during the meeting. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

7.4 Draft BPC opinion on coumatetralyl for PT 14

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The applicant informed that the manufacturing site has changed since the first approval and the new 5-batch analysis (BA) data were submitted in 2012. A decision on technical equivalence was granted by France in 2014. Based on this the applicant questioned the need to submit Quality Control (QC) data. This will be clarified by ECHA.

It was mentioned that analytical methods will not be re-evaluated in the light of new guidance during the renewal process. The general discussion will take place at the APCP WG in relation to the requirements at the active substances renewal stage. It was agreed that the eCA will check if such requirement was made during the first approval andif yes, relevant information should be included now in the AR and new data submitted as soon as possible, but not later than by the next renewal.

With reference to the P criterion it was agreed to discuss this issue at the ENV WG. Then all necessary data might be submitted by the next renewal, if applicable.

One member pointed out that the maximum nominal concentration of coumatetralyl used in contact formulations should be indicated in the opinion. Based on the discussion with

the applicant, the eCA proposed to add in the opinion the information that for contact formulation the nominal maximum concentration should not exceed 0.4 % w/w.

The BPC agreed that the residue data in non-target species are not sufficient to classify coumatetralyl as fulfilling the B criterion. This is in line with the conclusion made by the eCA in the Assessment Report and consistent with general agreements made for other rodenticides to discuss further requirements at WG stage. One member did not agree to this conclusion, because the conclusion was opposite to what was concluded for another anticoagulant rodenticide for which it was decided that the B criterion was fulfilled and where the residue data in the non-target species was taken into account.

With reference to comments made on a water-sediment study and soil simulation study the BPC followed the previously made general approach to discuss this issue at ENV WG level. If applicable, these studies will be required by the next renewal.

The Assessment Report was agreed subject to the changes agreed during the meeting. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

7.5 Draft BPC opinion on warfarin for PT 14

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The eCA informed that they requested a new 5 BA data and received Certificates of Analysis, which, in the opinion of the applicant, is sufficient to prove that the manufacturing process has not changed. In accordance with the general agreement, the new 5 BA should be submitted by October 2016.

The applicant questioned the need for submission of a new analytical study, claiming that they were evaluated as sufficient at the product authorisation stage and there is no need to repeat the whole study in case one data point is missing. The eCA pointed out that this is a standard practice, but in accordance with the general agreement the eCA agreed to highlight it now and require a new study by the next renewal.

Following previously made agreements on the residue data in non-target species, it was decided that they are not sufficient to classify warfarin as fulfilling the B criterion.

The use of loose grain and pellets in sachets for trained professionals against voles and field mice was questioned by the applicant as unpractical and decreasing the attractiveness of the bait. The eCA pointed out that use against voles was not assessed for warfarin for the first approval as well as for renewal of approval and this should be done at product authorisation stage. This was agreed by the BPC.

The eCA was of the opinion that for warfarin some precautionary principles in relation to resistance should be taken into account. At best, as it is a complex issue, the use of products containing warfarin against mice should be restricted only to trained professionals. The Chairman pointed out that this issue was harmonised during the general discussion on rodenticides. The BPC agreed that products containing warfarin will not be banned for use against mice.

It was agreed not to make reference to alien species in the opinion, as instead was proposed by the applicant, as they were not assessed during the active substance approval. This might become an issue at product authorisation stage or in case of high invasion an emergency procedure will apply.

The Assessment Report was agreed subject to the changes agreed during the meeting. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

7.6 Draft BPC opinion on bromadiolone for PT 14

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had objections to the presence of ASOs during the discussion. The session was therefore kept closed.

The Assessment Report was agreed subject to the changes agreed during the meeting. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

7.7 Draft BPC opinion on difenacoum for PT 14

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had objections to the presence of ASOs during the discussion. The session was therefore kept closed.

The Assessment Report was agreed subject to the changes agreed during the meeting. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

7.8 Draft BPC opinion on brodifacoum for PT 14

The Chairman welcomed both applicants for this item and informed that two dossiers were submitted to Italy and to the Netherlands, respectively. The Chairman noted that the applicant had objected to the presence of ASOs during the discussion. The session was therefore kept closed.

The Assessment Report was agreed subject to the changes agreed during the meeting. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

7.9 Draft BPC opinion on difethialone for PT 14

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had objections to the presence of ASOs during the discussion. The session was therefore kept closed.

The Assessment Report was agreed subject to the changes agreed during the meeting. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

7.10 Draft BPC opinion on flocoumafen for PT 14

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had objections to the presence of ASOs during the discussion. The session was therefore kept closed.

The Assessment Report was agreed subject to the changes agreed during the meeting. The opinion was adopted by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

7.11 Draft BPC opinion on cyanamide for PT 3 and 18

The Chairman welcomed the Applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The Rapporteur introduced the substance and the general issues related to the assessment report (AR) and opinion were then discussed in detail (modifications are described in the open issues table).

The Rapporteur accepted the request by the Applicant to include a statement that with respect to data on efficacy field tests, semi-field tests, and simulated tests have not been performed. Furthermore, it was clarified that for PT 18 only a simulated-use test is required for product authorisation. On the dermal absorption values used for the phases of mixing & loading and application, the Rapporteur explained why the same value of 25% had been used for the whole process. The approach was based on two available studies for the whole working day, for which the number of mixing & loading events was 40 in one study and 2 in the other study, where the hand exposure was the same. This has led the Rapporteur to conclude that the hand exposure was not driven by the mixing and loading phase but by the application phase and therefore the 25% was used for the exposure assessment. The member raising the issue agreed to the approach but requested to be clearly stated in the CAR that only the dermal adsorption value of 25% has been used in the calculations. The Rapporteur agreed to add this clarification.

The Rapporteur justified the need to add very specific information about the protective gloves with the fact that a study showed that cyanamide can easily penetrate different types of materials. It was proposed to state that the PPE indicated are examples of appropriate protective gloves and that in case other PPE are proposed the same safety level is demonstrated via appropriate testing. It was concluded that a similar statement would be included in the opinions adding also that other types of PPE were tested. In addition it was concluded that in section 2.4 of the opinion it has to be stated that "the properties of the substance should be taken into account" when selecting the appropriate PPE.

A member stated that an explanation needs to be added in the opinion, to justify why an active substance technically meeting the exclusion criteria can still be proposed to be approved; the reason being in this case that the draft CAR was submitted before 1 September 2013. This proposal was supported by several other members. A member stated that no risk assessment for food and feed areas has been done and questioned whether it should be added for both PT 3 and 18, that such risk assessment may be required at the product authorisation where the use of the product may lead to contamination of food and feed stuff. This was agreed, also being in line with other opinions.

The member from Denmark stated they would not support the approval of the substance for PT 3 nor 18 based on the fact that it is considered to have endocrine disrupter properties and that according to national information there are alternatives to the substance. The member from Sweden indicated that this substance has not been used for 30 years in Sweden. COM reacted to state that these contributions should in fact have been made during the public consultation, as no alternative substances had been declared during that phase. It was acknowledged that Member States should give timely attention to public consultations in the future.

COM commented that the BPC should indicate if there are other substances already approved which were assessed for the same use, given that cyanamide is a candidate for substitution. Acknowledging that such assessment will need to be done in the future, the Chairman concluded that at this point in time it is possible to include such information in the opinion only for PT 3. COM also asked the BPC to consider whether the statements of the members from Denmark and Sweden should be added in the opinion concerning the absence of use on their market, considering that the BPC opinion should also reflect the expertise of its members. The Chairman and BPC members concluded that it should not be added as it came late in the process.

As cyanamide is meeting the exclusion criteria with respect to the interim ED criteria, the applicant requested clarification on what will happen when the final ED criteria are set and cyanamide turns out not to be an ED substance. COM explained that in this case the applicant request COM to initiate an Article 15 procedure to amend the approval.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting. The BPC adopted the opinions for PT 3 and PT 18 by majority.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.
- The member from **DK** to submit their minority positions for PT3 and PT18 within 7 days.

7.12 Draft BPC opinion on piperonyl butoxide for PT 18

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had objected to the presence of ASOs during the discussion. The session was therefore kept closed.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting. The BPC adopted the opinion by majority.

The two members that do not support the approval of PBO will submit their minority positions within 7 days.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.
- The **members** that do not support the approval of PBO to submit their minority positions within 7 days.

7.13 Draft BPC opinion on *epsilon*-Momfluorothrin for PT 18

The Chairman welcomed the applicant for this item. The Chairman noted that the applicant had not objected to the presence of ASOs during the discussion. The session was therefore kept open.

The rapporteur introduced the substance and the general issues related to the assessment report (AR) and to the opinion were then discussed in detail (modifications are described in the open issues table).

Epsilon-momfluorothrin is a new active substance. The applicant was asked when the requested new data could be submitted in order to set the approval date. As the new 5 batch analysis will only become available within several years it was clarified that an application for technical equivalence assessment under Article 54 of the BPR will have to be submitted in due time. This will be explained in the opinion.

The Assessment Report was agreed by the BPC, subject to the changes agreed during the meeting. The BPC adopted the opinion by consensus.

Actions:

- **Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.**
- **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.
- **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish it on the ECHA website.

8. Union authorisation

8.1 Working procedure for Union authorisations

The document was not discussed.

Actions:

- **SECR:** to open a newsgroup in CIRCABC for commenting

8.2 Discussions and issues concerning Union authorisation expected at Working Groups and BPC meetings

The document was postponed to the next BPC meeting.

9. Any other business

9.1 Additional data received for copper, granulated after the approval

The Chairman informed the meeting that FR has received additional data after the approval of copper, granulated. According to the BPC document "Procedure for the submission, evaluation and dissemination of data generated after active substance approval" the SECR will initiate a consultation period.

Actions:

- **SECR:** to open consultation period for the additional data received after active substance approval

10. Agreement of the action points and conclusions

Part II contains the main conclusions and action points which were agreed at the meeting.

Part II - Main conclusions and action points

Agreed at the 16th meeting of BPC

14-16 June 2016

Agenda point	
Conclusions / decisions / minority positions	**Action requested after the meeting (by whom/by when)**
Item 2 - Agreement of the agenda	
The final draft agenda was agreed without further changes.	**SECR:** to upload the agreed final agenda to the BPC CIRCABC IG as part of the draft meeting minutes after the meeting.
Item 4 - Agreement of the minutes and review of actions from BPC-15	
The revised version of the minutes of BPC-15 was agreed as proposed subject to several editorial modifications.	**SECR:** to upload the agreed minutes to the BPC CIRCABC IG and to the ECHA website after the meeting.
Item 5 – Administrative issues	
5.2 Administrative issues	
-	
5.3 Update on ECHA's policy on prevention and management of potential conflicts of interest	
-	
5.3 Establishment and mandate for Ad-hoc Working Group on Micro-organisms (Ad Hoc WG MO)	
The mandate for the Ad-hoc Working Group on Micro-organisms was agreed.	SECR: - to make the mandate available via CIRCA BC and the ECHA web-site - to initiate the nomination process for the Ad Hoc WG MO
Item 6 - Work programme for BPC	
6.1. Revised Work Programme 2016-2017	
	Members: to send information on any further changes to the Work Programme (WP) to the SECR **by 23 June 2016**. **SECR:** on the basis of the changes to update the WP on the ECHA web site and in the BPC CIRCABC IG.
6.2. Outlook for second priority list	

	Members: to send information on their planning for the second priority list further changes to the SECR by **15 August 2016**.
Item 7 - Applications for approval of active substances	
7.1.a) Catalogue of specific conditions and elements to be taken into account at the product authorisation stage	
-	
7.1.b) Revision of working procedure for active substance approval following BPC-15	
The revised working procedure for active substance approval was agreed.	**SECR**: to make the revised working procedure available via CIRCA BC and the ECHA web-site
7.2 Draft BPC opinion on peracetic acid for PT 11 and 12	
The BPC adopted by consensus the opinions for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish them on the ECHA website.
7.3-7.10 General discussion on anticoagulant rodenticides	
SECR: • to initiate a discussion at the next Coordination Group meeting on information requirements for dermal absorption for the renewal of product authorisation; • to initiate a discussion at the Working Group Environment on information requirements with respect to the next renewal of active substance approval; • to initiate a discussion at the Working Group APCP on information requirements for renewal of active substance approval in general.	
7.3 Draft BPC opinion on chlorophacinone for PT 14	
The BPC adopted by consensus the opinion for the renewal of this active substance/PT combination. The substance meets the exclusion criteria laid down in Article 5 of the BPR. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) and 10(1)(e) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
7.4 Draft BPC opinion on coumatetralyl for PT 14	

The BPC adopted by consensus the opinion for the renewal of this active substance/PT combination. The substance meets the exclusion criteria laid down in Article 5 of the BPR. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) and 10(1)(e) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
7.5 Draft BPC opinion on warfarin for PT 14	
The BPC adopted by consensus the opinion for the renewal of this active substance/PT combination. The substance meets the exclusion criteria laid down in Article 5 of the BPR. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) and 10(1)(e) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
7.6 Draft BPC opinion on bromadiolone for PT 14	
The BPC adopted by consensus the opinion for the renewal of this active substance/PT combination. The substance meets the exclusion criteria laid down in Article 5 of the BPR. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) and 10(1)(e) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
7.7 Draft BPC opinion on difenacoum for PT 14	
The BPC adopted by consensus the opinion for the renewal of this active substance/PT combination. The substance meets the exclusion criteria laid down in Article 5 of the BPR. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) and 10(1)(e) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
7.8 Draft BPC opinion on brodifacoum for PT 14	
The BPC adopted by consensus the opinion for the renewal of this active substance/PT combination. The substance meets the exclusion criteria laid down in Article 5 of the BPR. The substance is considered a candidate for	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur.

substitution in accordance with Article 10(1)(a) and 10(1)(e) of the BPR.	**SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
7.9 Draft BPC opinion on difethialone for PT 14	
The BPC adopted by consensus the opinion for the renewal of this active substance/PT combination. The substance meets the exclusion criteria laid down in Article 5 of the BPR. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) and 10(1)(e) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
7.10 Draft BPC opinion on flocoumafen for PT 14	
The BPC adopted by consensus the opinion for the renewal of this active substance/PT combination. The substance meets the exclusion criteria laid down in Article 5 of the BPR. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) and 10(1)(e) of the BPR.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
7.11 Draft BPC opinion on cyanamide for PT 3 and 18	
The BPC adopted by majority the opinions for the approval of this active substance/PT combination. The substance is considered a candidate for substitution in accordance with Article 10(1)(a) of the BPR.	**Rapporteur:** to revise the assessment reports in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **Member**: to submit to SECR the minority positions by **23 June 2016.** **SECR:** to revise the draft opinions in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinions to COM **by 7 July 2016** and publish them on the ECHA website.
7.12 Draft BPC opinion on piperonylbutoxide (PBO) for PT 18	
The BPC adopted by majority the opinions for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **Member**: to submit to SECR the minority positions by **23 June 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
7.13 Draft BPC opinion on momfluorothrin (S-1563) for PT 18	

The BPC adopted by consensus the opinions for the approval of this active substance/PT combination.	**Rapporteur:** to revise the assessment report in accordance with the discussions in the BPC and submit to the SECR **by 28 July 2016.** **SECR:** to revise the draft opinion in accordance with the discussions in the BPC and carry out an editorial check in consultation with the rapporteur. **SECR:** to forward the adopted opinion to COM **by 7 July 2016** and publish it on the ECHA website.
Item 8 – Union authorisation	
8.1 Working procedure for Union authorisation	
	SECR: as the item was not discussed at the meeting to open a newsgroup in CIRCABC for commenting.
8.2 Discussions and issues concerning Union authorisation expected at Working Groups and Biocidal Product Committee meetings	
This item was postponed to the next BPC.	
Item 9 – Any other business	
	SECR: to open consultation period for the additional data received after active substance approval on copper, granulated.

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Part III - List of Attendees

Members	European Commission
Applicants	**Apologies**
BROVKINA Julija (LV)	LAS HERAS Alfonso (DG SANTE)
COR Gabrielle (ELFATECH S.A.S.) for bromadiolone PT 14, chlorophacinone PT 14 and difethialone PT 14	BRUYNDONCKX Raf (CEFIC)
CABALLO DIEGUEZ Covadonga (ES)	
ČEBAŠEK Petra (SI)	**Advisers**
GARTLAND Kevan (Sumitomo Chemical (UK) PLC) for cloethocarb PT 18 and momfluorothrin PT 18	CAZELLE Elodie (AISE)
	CARNEADO Francisco (ES)
GEHRMANN Hubertus (Arch Chemicals (Europe) BV) for cyanamide PT 3 and 18	ERIESEN Anton (DE)
	GIORDMAINA Wayne (MT)
HADJIGEORGIOU Andreas (CY)	GAUSTAD Astrid (NO)
HARRISON John (IE)	GREGG Nicola (UK)
JÄGER Martina (Kemira Oyj) for peracetic acid PT 11 and 12	GUSTAFSSON Kerstin (SE)
JÄGER Stefanie (DE)	HAHLBECK Edda (SE)
LODINI Sara (Activa S.r.l.) for brodifacoum PT 14	HAMALAINEN Anna-Maija (FI)
JOHN Nina (AT)	HYVARINEN Tuija (FI)
KOIVISTO Sanna (FI)	KARHI Kimmo (FI)
KOMEN Corine (NL)	MARTINEZ Marta (ES)
LARSEN Jørgen (DK)	PENTTINEN Sari (FI)
MERISTE Anu (EE)	PÜRGY Reinhild (AT)
MIKOLASKOVA Denisa (SK)	RITZ Vera (DE)
RUSCONI Manuel (CH)	TUUSA Tiina (FI)
SZANTO Emese (HU)	VAN GALEN Joost (NL)
VACEK Tomas	
VAN BERLO Boris (BE)	
Accompanying experts	
ZOUPOS Athanasios (Ed)	
Alternate members	**Accredited Stakeholder Organisations**
COLLET Romy (FR)	HYNES Jarlath (Humane Society International)
CRESTI Raffaella (IT)	MONTMOREAU Bertrand (CEPA)
DONS Christian (NO)	
ENSCH Svenja (LU)	**ECHA Staff**
IAKOVIDOU Mary (SE)	JANOSSY Judit
	NEGULICI Ligia
	SAEZ RIBAS Monica
Invited expert	SZYMANCKIEWICZ Katarzyna
HADAM Anna (PL)	VAN DE PLASSCHE Erik

ARMORS Kristina, accompanying expert for momfluorothrin PT 18

FOLLI Cristina, accompanying expert for piperonyl butoxide (PBO) PT 18

HOWARD Karen, accompanying expert for difenacoum PT 14, bromadiolone PT 14, coumatetralyl PT 14 and brodifacoum PT 14

LEUSCH Hans-Josef, accompanying expert for cyanamide PT 3 and 18

Part IV - List of Annexes

Annex I List of documents submitted to the members of the Biocidal Products Committee

Annex II Final agenda of BPC-16

Annex I

Documents submitted to the members of the Biocidal Products Committee for the BPC-16 meeting

Meeting documents			
Agenda Point	**Number**	**Title**	
2	BPC-A-16-2016_rev2	Draft agenda	
4	BPC-M-15-2015	Draft minutes from BPC-15	
5.2	BPC-16-2016-01	Administrative issues and report from the other Committees	
5.3	BPC-16-2016-22	Update on ECHA's policy on the prevention and management of potential conflicts of interest	
5.4	BPC-16-2016-23	Establishment and mandate for Ad-hoc Working Group on Micro-organisms (Ad Hoc WG MO)	
6.1	BPC-16-2016-02	BPC updated Work Programme 2016-2017	
6.2	BPC-16-2016-03	Outlook for second priority list	
7.1.a)	BPC-16-2016-04	Catalogue of specific conditions and elements to be taken into account at the product authorisation stage	
7.1.b)	BPC-16-2016-05	Revision of working procedure following BPC-15	
8.1	BPC-16-2016-20	Working procedure for Union authorisation	
8.2	BPC-16-2016-21	Discussions and issues concerning Union authorisation expected at Working Groups and Biocidal Product Committee meetings	
Substance documents			
Agenda Point	**Number**	**Substance-PT**	**Title**
7.2	BPC-16-2016-06A	Peracetic acid PT 11	Draft BPC opinion
	BPC-16-2016-06B		Assessment report
	BPC-16-2016-06C		Open issues
7.2	BPC-16-2016-07A	Peracetic acid PT 12	Draft BPC opinion
	BPC-16-2016-06B		Assessment report
	BPC-16-2016-06C		Open issues

7.3-7.10	BPC-16-2016-08C	Anticoagulant rodenticides	General open issues table for anticoagulant rodenticides
7.3	BPC-16-2016-08A	Chlorophacinone PT 14	Draft BPC opinion
	BPC-16-2016-08B		Assessment report
	BPC-16-2016-08D		Open issues
7.4	BPC-16-2016-09A	Coumatetralyl PT 14	Draft BPC opinion
	BPC-16-2016-09A_rev		Revised draft BPC opinion
	BPC-16-2016-09B		Assessment report
	BPC-16-2016-08C		Open issues
7.5	BPC-16-2016-10A	Warfarin PT 14	Draft BPC opinion
	BPC-16-2016-10A_rev		Revised draft BPC opinion
	BPC-16-2016-10B		Assessment report
	BPC-16-2016-08C		Open issues
7.6	BPC-16-2016-11A	Bromadiolone PT 14	Draft BPC opinion
	BPC-16-2016-11B		Assessment report
	BPC-16-2016-08C		Open issues
7.7	BPC-16-2016-12A	Difenacoum PT 14	Draft BPC opinion
	BPC-16-2016-12A_rev		Revised draft BPC opinion
	BPC-16-2016-12B		Assessment report
	BPC-16-2016-08C		Open issues
7.8	BPC-16-2016-13A	Brodifacoum PT 14	Draft BPC opinion
	BPC-16-2016-13B		Assessment report
	BPC-16-2016-08C		Open issues
7.9	BPC-16-2016-14A	Difethialone PT 14	Draft BPC opinion
	BPC-16-2016-14B		Assessment report
	BPC-16-2016-08C		Open issues
7.10	BPC-16-2016-15A	Flocoumafen PT 14	Draft BPC opinion
	BPC-16-2016-15B		Assessment report
	BPC-16-2016-08C		Open issues
7.11	BPC-16-2016-16A	Cyanamide PT 3	Draft BPC opinion
	BPC-16-2016-16B		Assessment report
	BPC-16-2016-16C		Open issues
7.11	BPC-16-2016-17A	Cyanamide PT 18	Draft BPC opinion
	BPC-16-2016-17B		Assessment report
	BPC-16-2016-16C		Open issues
7.12	BPC-16-2016-18A	Piperonylbutoxide (PBO) PT 18	Draft BPC opinion
	BPC-16-2016-18B		Assessment report

	BPC-16-2016-18C		Open issues
7.13	BPC-16-2016-19A	S-1563 (Momfluorothrin) PT 18	Draft BPC opinion
	BPC-16-2016-19B		Assessment report
	BPC-16-2016-19C		Open issues

10 June 2016
BPC-A-16-2016_rev2

Draft agenda

16th meeting of the Biocidal Products Committee (BPC)

14-16 June 2016

ECHA Conference Centre, Annankatu 18, Helsinki

Starts on 14 June at 09:30, ends on 16 June at 16:30

1. – Welcome and apologies

2. – Agreement of the agenda

BPC-A-16-2016_rev2
For agreement

3. – Declarations of potential conflicts of interest to agenda items

4. – Agreement of the minutes and review of actions from BPC-15

BPC-M-15-2015
For agreement

5. – Administrative issues

5.1. Housekeeping issues

For information

5.2. Other administrative issues and report from other ECHA Committees

BPC-16-2016-01
For information

5.3. Update on ECHA's policy on the prevention and management of potential conflicts of interest

BPC-16-2016-22
For information

5.4. Establishment and mandate for Ad-hoc Working Group on Micro-organisms (Ad Hoc WG MO)

BPC-16-2016-23
For agreement

6. – Work programme for BPC

6.1. Revised BPC Work Programme 2016-2017

BPC-16-2016-02

For information

6.2. Outlook for second priority list

BPC-16-2016-03

For information

7. – Applications for approval of active substances*

7.1. a) Templates and formats for active substance approval: Catalogue of specific conditions and elements to be taken into account at the product authorisation stage for active substance approval

BPC-16-2016-04

For information

b) Revision of working procedure for active substance approval following BPC-15

BPC-16-2016-05

For agreement

7.2. Draft BPC opinion on peracetic acid for PT 11 and 12

Previous discussion(s): WG-II-2016

PT 11: BPC-16-2016-06A, B, C

PT 12: BPC-16-2016-07A, BPC-16-2016-06 B and C

For adoption

7.3. Draft BPC opinion on chlorophacinone for PT 14

Previous discussion(s): WG-I-2016

BPC-16-2016-08A, B, C, D

For adoption

7.4. Draft BPC opinion on coumatetralyl for PT 14

Previous discussion(s): WG-I-2016

BPC-16-2016-09A, A_rev, B and BPC-16-2016-08C

For adoption

7.5. Draft BPC opinion on warfarin for PT 14

Previous discussion(s): WG-I-2016

BPC-2016-16-10A, A_rev, B and and BPC-16-2016-08C

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* For the discussions of the draft BPC opinions at least the following documents will be distributed: a draft BPC opinion (denoted by A), a draft assessment report which may cover more than one PT (denoted by B) and a document containing open issues covering all the PTs to be discussed for that substance (denoted by C).

For adoption

7.6. Draft BPC opinion on bromadiolone for PT 14

Previous discussion(s): WG-I-2016

BPC-16-2016-11A, B and and BPC-16-2016-08C

For adoption

7.7. Draft BPC opinion on difenacoum for PT 14

Previous discussion(s): WG-I-2016

BPC-16-2016-12A, A_rev, B and and BPC-16-2016-08C

For adoption

7.8. Draft BPC opinion on brodifacoum for PT 14

Previous discussion(s): WG-I-2016

BPC-16-2016-13A, B and and BPC-16-2016-08C

For adoption

7.9. Draft BPC opinion on difethialone for PT 14

Previous discussion(s): WG-I-2016

BPC-16-2016-14A, B and and BPC-16-2016-08C

For adoption

7.10. Draft BPC opinion on flocoumafen for PT 14

Previous discussion(s): WG-I-2016

BPC-16-2016-15A, B, C and and BPC-16-2016-08C

For adoption

7.11. Draft BPC opinion on cyanamide for PT 3 and 18

Previous discussion(s): WG-I-2016

PT 3: BPC-16-2016-16 A, B, C

PT 18: BPC-16-2016-17 A, B and BPC-16-2016-16C

For adoption

7.12. Draft BPC opinion on piperonylbutoxide (PBO) for PT 18

Previous discussion(s): WG-II-2016

BPC-16-2016-18A, A_rev, B, C

For adoption

7.13. Draft BPC opinion on momfluorothrin (S-1563) for PT 18

Previous discussion(s): WG-II-2016

BPC-16-2016-19 A, B, C

For adoption

Item 8 – Union authorisation

8.1. Working procedure for Union authorisation

BPC-16-2016-20

For discussion

8.2. Discussions and issues concerning Union authorisation expected at Working Groups and Biocidal Product Committee meetings

BPC-16-2016-21

For discussion

Item 9 – Any other business

9.1 Additional data received for copper, granulated after the approval

Item 10 – Agreement of the action points and conclusions

For agreement