Via this document ECHA is reporting on the progress of the tasks for which ECHA is task leader.

1. TASKS RELATED TO GUIDANCE DEVELOPMENT

This contains several tasks. Below the progress for the different tasks is described where for the guidance on technical equivalence also the progress on the operational ECHA activities for applications for technical equivalence under Article 54 is described.

The tasks in relation to guidance development corresponding to the Biocides Implementation Projects (BIP) 6 projects as defined by ECHA overlap with the work on the overall guidance update launched by ECHA within the new guidance structure in support of the BPR (see Appendix 1). According to this new guidance structure, there will be two procedural guidance and four major scientific guidance documents. The compilation of the parts of the scientific guidance overlaps with and replaces the work on the BIP 6.4 project. The first chapters of the human health assessment section of the scientific guidance have been forwarded to the TM I 2013 for consultation. The work on the scientific guidance with regard to the efficacy of treated articles is considered a lower priority and has been put on hold. For the progress on the procedural guidance see Task 4 and 10 below.

Tasks 2 and 8: Regulation on exposure based waiving for active substances and biocidal products and Task 32 Guidance in relation to Articles 6.4 and 20.3

These tasks have been temporarily put on hold in relation with the progress of the development of regulations on exposure based waiving.

Task 4: Technical guidance notes to facilitate the implementation of the Chapter on approval of active substances, in particular Articles 5(2) and 10(1)
The Commission is leading the drafting of these technical guidance notes and ECHA will contribute when appropriate. This concerns in particular the interpretation of the criteria set out in the Article 10(1) of the BPR (on candidates for substitution).

To complement the new structure of guidance, ECHA has started drafting the procedural guidance for active substance approval under this task. The drafting has been delayed due to other priorities; however it will be resumed as soon as possible.

**Task 10: Technical guidance notes for the implementation of the Chapter on general principles for the product authorisation in particular Article 22(2) and 23(3).**

The Commission’s technical guidance notes on Articles 22(2) and 23(3) have been put on hold.

ECHA is currently progressing with the drafting of the procedural guidance for applications for authorisation of a biocidal product (family). A stakeholder consultation on the draft is foreseen in Q3 or Q4 2013 but will depend on the resources available. The CA meeting will be provided an opportunity to comment on the guidance in parallel with the stakeholder consultation.

**Task 14: Technical guidance notes on the assessment of technical equivalence**

A consultation with the Expert Group took place on 17th January 2013. Additional consultation with industry on technical equivalence assessments for organic peroxides took place on 22nd January 2013. A TM consultation on the revised draft will take place at TM I 2013. It is intended to organise a stakeholder consultation on the draft in Q2 2013. The guidance is planned to be published by the application date. The CA meeting will be provided the opportunity to comment on the guidance in parallel with the stakeholder consultation.

Following the consultation with the Expert Group ECHA would like to state that:

- remaining issues after the consultation are: data requirements for the assessment of technical equivalence (related to the necessity to have the spectral data for the alternative sources); technical concentrates versus dry material and assessment for organic peroxides.
- no consultation is foreseen with MS on the ECHA draft decision on technical equivalence as this is not foreseen in Article 54. ECHA will inform the MS (Article 54(3)) via the R4BP when an application is received and communicate the ECHA decision (Article 54(4)). If more
information is required by ECHA on the reference source, ECHA may consult with the RMS who carried out the evaluation of the original dossier (Article 54(6)).

- during the consultation several MS experts invited ECHA to consult them on technical equivalence assessments. ECHA clarified that it is not the intention to consult MS on individual applications but that ECHA is looking for a platform to discuss with MS generic issues related to the assessment of technical equivalence. This is considered relevant as MS can be confronted with unclear situations during the approval process, especially in cases of multiple applicants or when the applicant is a consortium, where there is a need for harmonisation.

ECHA is working with DG JRC on an inventory of reference sources for those active substance PT combinations included on Annex I of the BPD. All information available at DG JRC has now been transferred to ECHA. The next step will be the extraction of the relevant information for the reference source for Tier I assessments. In order to obtain all the relevant information ECHA may consult with the relevant RMS.

Following the discussion that took place at the December 2012 CA meeting, ECHA will report its views on the feasibility of assessing technical equivalence before the reference source of active substance is approved at the February 2013 CA meeting.

Task 28: Technical guidance regarding the application of Annex II and the preparation of the dossier for the active substance and Task 29 Technical guidance regarding the application of Annex III and the preparation of the dossier for the biocidal product

Following the comments received on the draft guidance at TM III and IV 2012, ECHA revised the draft guidance and submitted it for final discussion at TM I 2013. It is intended to organise a stakeholder consultation on the draft in Q2 2013. The guidance is planned to be published mid 2013. The CA meeting will be provided the opportunity to comment on the guidance in parallel with the stakeholder consultation. The publication of the guidance may happen stepwise should there be issues that require further consideration by the TM, i.e. parts of the guidance may be published with some delay.

Task 30: Technical guidance on the use of (Q)SARs and Task 31 Technical guidance on technically and scientifically justified methodology for the grouping of substances

As mentioned in the previous progress report no separate guidance for biocides will be developed on (Q)SARs and grouping by ECHA before the
application date of the BPR.

Task 33: Technical guidance related to Annex VI on the common principles for the evaluation of dossiers for biocidal products

As mentioned in the previous progress report the drafting of the guidance has been put on hold to concentrate the resources on higher priority work.

Task 34: Technical guidance on cumulative and synergistic effects

In the new structure of the guidance the results of these tasks will be part of the scientific guidance. The task has been split into several work packages for either human health or environmental assessment. The draft results of the work packages related to the mixture toxicity assessment (multiple substances from single products) for environmental assessment (E1) were discussed at TM III 2012 and for human health assessment (H1) at TM IV 2012. The drafts are revised and will be submitted again for discussion at TM I 2013 for endorsement. Considering the limited resources available in ECHA and JRC and the need to progress quickly with tasks of higher priority, it is likely that further processing of the work package on mixture toxicity as well as the work on the remaining work packages (E2 and H2: aggregated exposure and E3 and H3: multiple substances from multiple products) will be put on hold in 2013.

2. Task 36: Communication strategy and helpdesk

ECHA has recently launched a call via its web-site for expressions of interest for stakeholders to become Accredited Stakeholder Organisations. A Biocides Stakeholders’ Day is planned for June 2013.

The first web pages were published upon entry into force of the BPR (http://echa.europa.eu/regulations/biocidal-products-regulation). Further extension of the web pages is foreseen in 2013. Biocides terminology is now included in the multilingual “ECHA-Term database” to support companies in getting familiarised with the new legislation.

ECHA’s communications vehicles regularly cover topics related to the Biocidal Products Regulation.

In view of the need to embrace current and new legislative tasks efficiently and effectively while adapting to current resource constraints, ECHA is proposing to provide support to national biocides helpdesks via the enlargement of HelpNet. Currently HelpNet is the Network of REACH and CLP Helpdesks. In order to enlarge HelpNet to include also the biocides national helpdesks, an agreement from the HelpNet Steering Group is required.
In the context of the envisaged enlargement of HelpNet, ECHA has identified required preparatory tasks. These include the adaptation of the HelpNet Exchange (HelpEx) platform for biocides and the review of HelpNet Operating Procedures and Mission Statements. HelpEx is a platform allowing national helpdesks to discuss difficult questions, in particular when harmonisation of answers is required. It is managed and maintained by ECHA and currently used by national REACH and CLP helpdesks. When the BPR enters into operation, it will be beneficial for the national biocide authorities to have access to this tool. In the context of the foreseen enlargement of the HelpNet, the HelpEx tool needs to be further developed to serve this purpose. This is necessary to adequately classify biocide questions for discussion and in the knowledgebase.

The HelpNet Secretariat has approached the national biocide helpdesks and biocide MSCAs of Finland, France, Germany, Ireland, the Netherlands and the United Kingdom for support in this task. Their contribution is being sought by means of a dedicated working group of the HelpNet. The deadline to confirm participation in the working group is 15 February 2013.

According to the preliminary timetable, a decision on a Biocides HelpNet could be taken at the 8th HelpNet Steering Group meeting in Q4/2013 and national biocides helpdesks integrated into HelpNet at the 9th HelpNet Steering Group meeting in Q2 2014.

The ECHA Helpdesk Unit has also plans to prepare a short guidance note on how support and network activities are envisaged to be organised to be presented to the MSCAs during Q2 of 2013.

3. Task 37 and 38: IT and IUCLID

See separate reporting.

4. Task 39: Biocidal Products Committee and Coordination Group

An invitation for Member States to appoint BPC members was sent in October 2012 to the Permanent Representations of the EU Member States, EEA countries and to Croatia to invite them to appoint their members, alternate members or observer (Croatia). So far appointees were received from all Member States except Bulgaria, the Czech Republic, the Slovak Republic, Lithuania, Luxemburg, Poland and the EEA countries: Iceland and Liechtenstein. ECHA is consulting with Member States who did not appoint their member yet, especially those who are a RMS in the Review Programme. The participation of Switzerland is pending the revision of the mutual recognition agreement. In 2013 three preparatory meetings of the
BPC are scheduled in Helsinki: March 26-27, May 29-30 and October 9-10. Invitations were sent out in February for the first BPC meeting. The BPC rules of procedure and working procedures for the approval of active substances (new actives under the BPR and existing active substances of the Review Programme) are being developed for the first meeting of the BPC.

Following the discussion at the December CA meeting on the Coordination Group (CG), a questionnaire was sent to CAs inviting their perspective on the current PA & MR FG and the wishes for the future CG. At the time of preparing this report ECHA received 12 replies. ECHA is working closely with DG ENV to prepare a revised discussion paper which is to be presented at the February CA meeting.

5. Task 40: Data sharing

The implementation of the data sharing provisions of the BPR has started. A scoping document on data sharing has been available since early 2012. The responsibility to facilitate contacts between the applicants and data owners lies with the data submitters. In order to fulfil its tasks (i.e. “verify whether the data requested has been submitted with a previous application” and [...] “without delay, communicate the name and contact details of the data submitter(s) and data owners to the applicant”), ECHA plans to take over the list of contact persons of data owners and submitters, maintained so far by DG ENV. For now, DG ENV asked the original participants of the Review Programme to notify them about their updated contact details via the R4BP platform. This will then be handed over to ECHA.

6. Task 41: Dissemination

‘Historical data’ (submitted under the BPD i.e. until 31 August 2013): ECHA has identified the first active substance dossiers that it needs to disseminate (either because they are already included in Annex I or because they are close to inclusion). ECHA has tried to identify (with the help of the MSCAs) the contact details of the applicants and has contacted these applicants asking them to provide a non-confidential version of Doc IIIA for these dossiers by 1 July 2013. This will enable ECHA to carry out the final processing and to publish the data on 1 September (for those dossiers that will have been approved on that date).

‘New data’ (submitted under the BPR i.e. as from 1 September 2013): ECHA organised a workshop on biocides dissemination in Brussels on 15 January 2013. ECHA presented their work and planning on biocides dissemination to the relevant stakeholders (i.e. MSCAs, NGOs and industry) and provided them with the opportunity to share their own views on the topic. ECHA also
made a proposal for filter rules for the IUCLID fields to be used for disseminating biocides dossiers that will be submitted under the BPR and is currently awaiting feedback on the proposal in order to elaborate it further.

7. Task 42: Alternative suppliers

A guidance note is prepared by ECHA for the February 2013 CA meeting on the implementation of Article 95. In addition DG ENV has launched the information gathering process on contact details for the participants in the Review Programme (participant, data submitter and relevant person) via the current R4BP.

8. SPC quality check on translations for Union authorisation

As mentioned in the previous progress report ECHA foresees to start preparations for a working group in the second half of 2013.
Appendix 1: Correlation between BIP6 projects, tasks defined by the DG ENV and the new guidance structure.

<table>
<thead>
<tr>
<th>BIP6</th>
<th>Task</th>
<th>Description</th>
<th>Guidance packages according to new guidance structure</th>
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<td>Part A Part B Part C Horizont ref. ref. -</td>
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<td>V Procedural volumes AS BP TGN</td>
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<td>28, 29</td>
<td>Data Requirements: 1. Guidance for Annex II 2. Guidance for Annex III (data waiving in column 3 will be dealt with in this project)</td>
<td>AS&amp;BP - - Horizontal Ref. Ref. -</td>
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<td>2, 8, 30, 31, 32</td>
<td>Data waiving Annex IV 1. Use of QSARs (QSARs) 2. Grouping of substances 3. Criteria established in accordance with Articles 6(4) and 21(3).</td>
<td>AS&amp;BP - - QSAR Ref. Ref. (Tasks 2&amp;8 delegated act)</td>
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<td>10</td>
<td>Product Authorisation</td>
<td>- BP BP - - Core of the guidance Yes</td>
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<td>6</td>
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<td>Common Principles implementation of Annex VI</td>
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<td>7</td>
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<td>Common Principles cumulative and synergistic effects</td>
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Volumes I-IV of scientific guidance will be divided between I Physchem, II Efficacy, III Human health toxicity, and IV Environment.

Volume V of scientific guidance is to cover guidance which is not linked to a specific scientific area.

AS = active substance
PB = biocidal product
Ref. = reference from scientific guidance or TGN
TGN = “technical guidance notes” as defined by BPR.