**Guidance priorities**

**General**

Following previous discussions in the CA meeting ECHA identified what it considers as key priorities for 2020-2021 regarding biocides guidance development. The priorities have been selected from the pool of topics identified by different fora – BPC and its working groups, CG and CA meeting (including e-consultations in 2019 where NL, SE and DK provided written comments) as well as the Commission. In addition, following the 86th CA meeting in November 2019, SE submitted additional comments related to this document. The complete pool of topics can be found in CA-Feb20-Doc.7.2.b.2.

Items proposed in the e-consultations that raise some questions on whether they are in ECHA’s remit, scope or are needed, are in green and yellow rows. No reactions have been received from other MS on these proposals so far.

**Guidance activities binding ECHA guidance resources in 2020-2021**

There are couple of guidance documents which are a must to be addressed due to changes in the legal text (BPR), CA agreements or needs for ongoing assessments:

1. WG recommendation on *“In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors”*  - adaptations for product authorisation purposes
2. *Guidance on information requirements* – update of the guidance with regard to changes in the Annexes II and III of BPR (only Human Health affected in 2020)

In addition ECHA’s resources available for guidance development will be largely occupied by the following guidance related tasks:

1. Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR Development of a "Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides"
2. Mandate to EFSA and ECHA for scientific and technical assistance to develop a *Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water*

Furthermore, in relation to the *major update of EUSES* (2020-2021), there could be a need to address some guidance issues triggered in order to harmonise the guidance under REACH and BPR (ENV).

*ECHA proposes to postpone the work on the extension of Volume V, Guidance on Disinfection By-Products to other PTs until sufficient progress has been made on the Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water in order to use the capacity developed in the latter guidance.*

With the above must-to-do list, ECHA’s guidance resources in particular for Human Health and Environment are already significantly stretched for 2020-2021.

**Other guidance key priorities**

In addition to the above, and while there is limited capacity to deal with all high priority topics ECHA selected as particularly important other (quasi) guidance among the guidance documents already considered of high priority.

The following table lists the guidance documents considered as key priorities for the next two years and provides an indication of the scientific area affected and ECHA’s expectations on the input of MS.

To address the limitations for ECHA to support some of the above mentioned high priorities topics, MS need to provide resources to support actively their progress. MS should therefore reflect on the feasibility of their input in the guidance projects presented in the table below. In the absence of adequate MS resources, the corresponding topics will be de facto de-prioritised.

**Action**

The members of the CA meeting are invited to share their views on ECHA’s proposal and to indicate whether they would volunteer to lead or support the drafting of some of the prioritised guidance documents.

|  | AREA AFFECTED: | | | |
| --- | --- | --- | --- | --- |
| Guidance name  Priority justification  Expected input | TOX | ENV | EFF | APCP |
| MUST-TO-DO guidance |  |  |  |  |
| WG recommendation on *“In situ generated active substances – Risk assessment and implications on data requirements for active substances generated in situ and their precursors”* - adaptations for product authorisation  Needed for applicants for product authorisation whose in situ AS approval dossiers are in the pipeline  ECHA and MS to draft specific topics, ECHA to coordinate | x | x | (x) | x |
| *Guidance on information requirements* – update  TOX – Urgent (significant changes in the information requirements)  ENV - not that crucial, i. e. start with identification of issues first, minor input needed in 2020, go on with guidance development in 2021 only  APCP - minor input needed in 2020, go on with guidance development in 2021 only  MS to draft (apart from ED topics), ECHA to coordinate, guidance to follow formal guidance approval procedure (ECHA) | x | (x) | (x) | x |
| Mandate Article 75 (1)(g) Development of a "Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides"  Politically sensitive topic, mandate imposing the deadline  Two year project (2020- 2021): Mandate requires ECHA to prepare the guidance on the above mentioned topic that has been also formally consulted. ECHA to coordinate and provide input. (Note that independent of the mandate, ECHA is currently following EFSA bee guidance update which would be utilised also in the guidance development). |  | x |  |  |
| Mandate – *“Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water”*  Politically sensitive topic, mandate imposing the deadline  Two years project: EFSA in lead, ECHA and MS to develop the content, coordinate the work. Guidance to follow formal guidance approval procedure (ECHA). | x | x |  | x |
| Guidance topics triggered by major update of EUSES project  May be required as an input for the EUSES major update project if issues common to biocides and REACH which require harmonisation appear (topics are not known at this point in time).  Input to be provided by ECHA, WG to be involved, timelines not possible to give now, but related to the EUSES major update scheduled for 2020-2021 (possibly also beyond). |  | x |  |  |
| OTHER HIGH PRIORITY GUIDANCE |  |  |  |  |
| *Extension of Volume V, Guidance on Disinfection By-Products to other PTs*  *For some PTs no guidance available, potential delays in product authorisation or narrower scope of the risk assessment*  *Proposed to put on hold until 2021-2022 when Guidance Document on the impact of water treatment processes on residues of active substances or their metabolites in water abstracted for the production of drinking water has been finalised.*  *MS to take over the item.* | *x* | *x* |  | *x* |
| Revision of Guidance on Substances of Concern  Recurring issues in product authorisation  CG e-consultation addressed already development needs, CG members to draft, ECHA to coordinate. Guidance to follow formal guidance approval procedure (ECHA) | x | x |  |  |
| Finalisation of ARTFood professional users guidance  Currently on hold, considered urgent for PT4 applications.  ARTFood to finalise (2020), Guidance to follow formal guidance approval procedure (ECHA) (2020-2021) | x |  |  |  |
| PT 18: Development of a proposal on how to use Fsim in an aggregated exposure assessment  PT related timelines provided in Annex III of the RPR  FR likely to develop the content, approval in the remit of WG |  | x |  |  |
| PT 19: review of default value for Fsim (worst case to apply the Fsim of PT 18 to PT 19?)  PT related timelines provided in Annex III of the RPR  FR likely to develop the content, approval in the remit of WG |  | x |  |  |
| Vol. II, Parts B+C, updates to PT19  Very limited information related to PT19 is in the current guidance. Needs to be updated, especially in relation to repellents against mosquitos.  MSs mainly in 1st half of 2020 and ECHA in the 2nd half. Guidance to follow formal guidance approval procedure (ECHA). |  |  | x |  |
| Vol. II, Parts B+C, updates to Appendix 4 -Overview of standards, test conditions and pass criteria (PT 1-5)  Harmonisation between efficacy criteria set out by efficacy guidance and EN standards is needed in the in areas where it is possible.  ECHA to provide input, Guidance to follow formal guidance approval procedure (ECHA). |  |  | x |  |